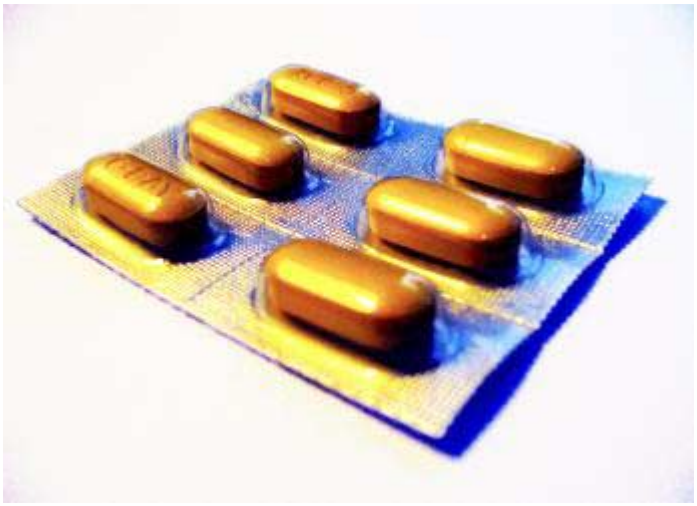


Can Illinois Residents and Businesses Safely and Effectively Purchase Prescription Drugs from Europe?

Prepared by: **Ram Kamath, Pharm.D. &**
Scott McKibbin
Office of the Special Advocates for Prescription Drugs
June 28, 2004
August 23, 2004 – Corrected p. 78

Rod R. Blagojevich, Governor of Illinois

TABLE OF CONTENTS

I. Executive Summary

Background

According to the World Health Organization, residents of the United States spend more money annually for health care than residents of any other country in the world. Yet their overall health outcomes are not consistent with that spending. Americans have shorter life expectancies, higher infant mortality rates, and higher child mortality rates than a number of countries, including Belgium, Canada, France, Germany, the Netherlands, and the United Kingdom.

The ever-increasing cost of prescription drugs has forced growing numbers of Americans, many of them elderly citizens living on fixed incomes, to buy essential medications from beyond U.S. borders. Each year, millions of Americans achieve some level of financial relief by purchasing prescription drugs from Canada, Mexico, Europe, and Southeast Asia. To date, however, individual Americans and businesses have not been able to obtain lower-cost prescription medication in an organized, regulated manner.

The recent development of Canadian Internet pharmacies has demonstrated the true demand for inexpensive medication. Researchers estimate that over six million Americans have obtained needed medicines from online Canadian pharmacies. Legislators recognized that high drug prices were forcing their constituents to buy from the Canadian market whether or not those actions were legal. They further realized that they had a civic duty to protect the health of U.S. residents who, by sole virtue of being less wealthy, could not afford to buy their doctor-recommended medications at current U.S. market prices.

On July 25, 2003, members of the U.S. House of Representatives voted for H.R. 2427 (the Pharmaceutical Market Access Act), which would require the secretary of the Department of Health and Human Services to develop regulations regarding prescription drug reimportation. Governor Rod Blagojevich commissioned a team of specialists to travel to Canada to evaluate the feasibility of State employees and retirees obtaining safe and effective medications from Canada. Team members reported that Canadian regulatory systems regarding public health and safety were substantially equivalent to those of the State of Illinois, and that Canadian methods of ensuring the safety and efficacy of prescription drugs were comparable to those of the United States. The report's authors estimated that a savings of $90.7 million could be achieved if the employees and retirees of Illinois were to purchase their maintenance medications from Canada. But when cities and states began to implement plans to help needy residents access low-cost Canadian medications, some drug companies responded by restricting or entirely stopping supplies to Canadian facilities that sell prescription drugs to Americans. The legality of these actions are currently being debated in court.

The pharmaceutical industry achieved a major victory when the Medicare Modernization Act of 2003 was signed into law. While the Act calls for the creation of a task force to study the issue of drug reimportation, it specifically prohibits the Medicare program from using its size to negotiate lower prices with drug manufacturers (as the Department of Veteran's Affairs does).

Public outcry against the high cost of prescription medication continued to grow in the face of accounts of Americans forced to choose between their medication and necessities like food and rent, and in the summer of 2004, the debate over drug reimportation transferred from the House to the Senate. Democrats, Republicans, and Independents alike forged an extraordinary alliance to address the reimportation issue.

Reimportation can take two forms: personal importation or parallel importation. Personal importation transpires when individuals purchase prescription drugs from foreign sources for their own personal use. Parallel importation takes place when medications are purchased in bulk in countries where prices are low and re-sold in countries where prices are higher. This kind of trade has been occurring in Europe since the mid-1970s, and it is largely based upon the free movement of goods between European Union (EU) member states. Many EU governments actively encourage parallel importation because of the cost savings it achieves.

In the Senate, three drug reimportation bills are currently being debated. S. 2328 (commonly known as the Dorgan-McCain-Kennedy-Snowe bill, and endorsed by the AARP), sponsored by Senator Byron Dorgan, would enable safe and prompt reimportation. S. 2328 recommends a reimportation plan with stringent safety measures that match or exceed those applied to domestic drug suppliers. Additionally, the bill prevents the pharmaceutical industry from blocking reimportation efforts and provides FDA with the funding it will need to ensure the safety of imported medication. S. 2328 could be strengthened with some additional fine-tuning. The bill currently restricts personal drug importation to Canada only, and does not consider other countries; this limitation provides less incentive for parallel importers to pass savings on to individual customers. Also, S. 2328 currently requires that participating facilities be inspected every three weeks; this provision could prove costly, and possibly unnecessary. FDA should be relied upon to use its expertise and judgment when determining appropriate inspection intervals.

The European Option

The decision of many pharmaceutical companies to limit drug supplies to Canadian facilities that provide prescription medications to Americans has induced an artificial shortage. Therefore, limiting a prescription drug importation model to Canada alone would not be desirable. Consequently, Governor Blagojevich directed his team to turn their research efforts to Europe. The European delegation, comprised of members of the Governor's office, the Office of the Special Advocates for Prescription Drugs, and the

Illinois Departments of Public Health and Professional Regulation, revisited the framework developed for their Canadian study. They also formulated additional questions and criteria specific to a European importation model. Their central policy question was, *Can Illinois residents and businesses safely and effectively obtain prescription medications from Europe?*

The delegation met with representatives from governments, manufacturers, pharmacies, wholesalers, parallel importers, health and insurance funds, and professional and trade associations in Belgium, France, Germany, Ireland, the Netherlands, and the United Kingdom. They methodically assessed pharmacy practices, pharmaceutical manufacturing, warehousing, storage, and distribution processes, and compared them to Illinois standards and practices. They also amassed information regarding regulatory processes and standards concerning the safety and efficacy of drugs and pharmacy practices, dispensing and drug costs, research and development concerns, pricing methodologies on a national basis, and processes of managing prescription drug utilization management. They determined that by participating in the European parallel importation system, Illinoisans could purchase drugs intended for the higher-cost countries of the European market and still capture substantial savings, even when shipping costs are taken into account. Most importantly, the delegation determined that all but one of the many European facilities visited demonstrated high quality standards of pharmacy practice, pharmacist qualifications, and storage, distribution, counseling, and manufacturing practices.

Analysis of Options

Four options were considered for recommendation by the Governor's delegation. Two were rejected outright, and one was deferred because of current implementation difficulties, in favor of one option that achieves safety and cost-saving goals.

- *Rejected: Maintain the Status Quo (Unregulated Personal Importation)*
  The delegation acknowledged that the current system of unregulated personal importation is neither viable nor safe. The existence of illegitimate Internet pharmacies both at home and abroad make the present situation unacceptable. Officials responsible for public health have an obligation to identify a safe solution to the as-yet-unsolved problem of pharmaceutical industry market abuse.

- *Rejected: State-Facilitated Access to Internet Pharmacies*
  Minnesota, Wisconsin, New Hampshire, and North Dakota have all provided links on their state websites that allow residents access to several Canadian Internet pharmacies. Yet some of these pharmacies have shipped drugs not approved for sale in the United States. This model provides neither the structure nor the funding needed to effectively and safely regulate personal importation.

- *Deferred: Parallel Importation Model*
  Parallel importation is currently infeasible because of existing law and the requirement of a larger commercial operation. Eventually, if the law changes, Illinois pharmacies and wholesalers could import certain prescription drugs and sell them to Illinois consumers. The delegation asserts that this could be done safely and cost-effectively.

- *Proposed: Web-Based Clearinghouse Network*
  This option contemplates a contractual relationship with a non-domestic, PBM (pharmacy benefits manager) type of entity that would act as a clearinghouse for all prescriptions filled through the non-domestic network (consisting of approved and vetted facilities in Europe and Canada). The State would provide a referral and link to the clearinghouse's website in exchange for regulated services and adherence to safety standards. The clearinghouse would also develop and maintain a custom website that enables consumers to compare prices for their prescription drugs from different approved foreign sources. This option would provide stringent safety precautions and consumer protections, and would also achieve significant cost savings for participants.

Financial Summary

Cost savings were estimated for residents who have employer-provided prescription drug coverage and for residents who lack drug coverage. The total projected twelve-month net savings for the State of Illinois and its employees and retirees range from **$94.9 million to $112.9 million,** depending on the country of drug origin. The State's savings amount would be between $49.3 million and $67.3 million (depending on the drug country of origin), and the employee/retiree amount would be $45.6 million. The projected savings for all other Illinois employers is $950.6 million. The projected savings for the Illinois uninsured is $851 million. If unlimited supplies were available for importation (Illinois would draw from a network of approved European providers to maximize supply), and if *all* Illinois residents used personal importation to meet their needs for selected program drugs, then the maximum potential savings—estimated with fairly conservative assumptions (other than full participation)—for the State of Illinois could be **$1.9 billion** for the first full year of program operation. A savings of roughly $1 billion would still be achieved even if only half of all eligible participants took part in the program. However, it is unrealistic to believe the pharmaceutical industry will not try to restrict supply wherever possible. It would be necessary to look beyond Europe to achieve full potential savings.

While the immediate magnitude of the savings estimates is clear, it is also important to address the larger effects that may ripple through other sectors. It is expected that Illinois retail pharmacies will lose some prescriptions to non-domestic pharmacies. However, only a limited number of drugs would be included in a personal importation model, and many drugs would remain available at local pharmacies only. Additionally, if Illinois

pharmacies and wholesalers could access the non-domestic parallel importation market and dispense imported pharmaceuticals to Illinois consumers, they would be largely shielded from any disadvantage. For this reason, in support of Illinois's retail pharmacies, the State should aggressively support the pending legislation that would enable domestic pharmacies to access lower-cost medications from abroad.

Furthermore, large cost savings for individuals participating in a prescription drug reimportation program translate into more money spent in the local economy. Finally, improved health outcomes are anticipated, as more individuals—both insured and uninsured—are better able to comply with drug therapy treatment as recommended by a physician.

Conclusion

Prescription drug prices are too high and unaffordable for many Illinoisans. Personal importation of medication through the Internet and mail-order programs enables Illinoisans—particularly seniors, the uninsured, and the under-insured—to directly lower their costs and increase their access to affordable prescription drugs. Because of the need for more affordable medication, personal importation is already growing rapidly, in spite of FDA concerns that the supply may be irregular or unsafe. The State of Illinois should act to assure that its citizens have sustained access to the highest quality and safety in prescription drugs at a greatly reduced expense. The State's regulatory and professional standards must be applied to ensure that personal importation is safe and effective for Illinoisans.

The current model of pharmaceutical purchasing and pricing must be abandoned in favor of a rational system that balances Illinoisans' access to affordable prescription drugs while allowing drug companies to continue meaningful research and development. The reimportation of drugs on both a personal and a wholesale basis would move Illinois—and the United States—toward this balance. Taxpayers can no longer afford to pay the highest prescription drug prices in the world and continue to subsidize the research and development costs of the pharmaceutical industry through tax credits.

The State of Illinois must continue to work closely with key Congressional leadership to enact balanced legislation that will ensure worldwide access to reasonably priced prescription drugs through both the personal importation model and the parallel importation model (accessed via a local pharmacy). Illinois must work with its counterparts in other states and countries to ensure continued access to the safe and effective medications that so many of the world's citizens require to maintain full and healthy lives.

II. Background

Residents of the United States spend more money on health care than residents of any other country in the world, yet that spending does not guarantee lower mortality rates or longer life expectancies (see Appendix 1). High prescription drug and health costs have long encouraged U.S. residents to take advantage of lower prices in other countries. Travelers to Canada and Mexico routinely bring back personal supplies of medication when they return to this country. Pharmacies have sprung up in border towns and near cruise ship ports. A recent Wall Street Journal article profiled India's growing "medical tourism" business.[1] Residents visiting family and friends in Southeast Asia and Europe often return with personal drug supplies, at times intended to last an entire year. Table 1 documents the rising costs of health spending in the United States.

Table 1
The Rise in U.S. Health Spending[2]

Year	$ Spent on Prescription Drugs (in billions of dollars)	Percent of Overall Health Spending
1990	$40.3	5.8%
1992	$48.2	5.8%
1994	$54.6	5.8%
1996	$67.1	6.5%
1998	$87.3	7.5%
2000	$121.5	9.3%
2002	$162.4	10.5%

Importation Restrictions and the Rising Cost of Drugs

Yet ever-stricter controls on the flow of prescription medication have been making their way into U.S. legislation. On February 24, 1987, FDA issued Import Alert # 60-01. The alert states,

> Minneapolis and Detroit districts recently reported activity in the importation of Canadian Tagamet…There is reason to believe that there may be attempts to enter Canadian Tagamet through other U.S. ports of entry as well. Smith, Kline & French Laboratories (USA) is concerned about such illegal importations and they are making every effort to stop them…Two shippers that have been identified… are wholesalers who do not purchase directly from the manufacturer, but from other wholesalers. Tagamet manufactured in Canada is considered a new drug which may only be imported/marketed in this country pursuant to an approved new

[1] Jay Solomon, "India's New Coup in Outsourcing Inpatient Care," *The Wall Street Journal*, April 26, 2004.
[2] Centers for Medicare & Medicaid Services, National Health Accounts, as reported in the online journal of the American Medical Association, http://www.ama-assn.org/amednews/2004/07/05/gvsa0705.htm.

> drug application (NDA). No such approval has been granted, nor is any application for approval on file with the Canadian facility…Because of significant price differential, an attempt may be made to import the generic product.[3]

The concern felt by Smith, Kline & French and noted in the Import Alert was communicated to legislators, and on April 22, 1988, the Prescription Drug Marketing Act of 1987 was signed into law by then-President Ronald Reagan. The law amends the Federal Food, Drug, and Cosmetic Act to "ban the reimportation of prescription human drugs produced in the United States, except when reimported by the manufacturer or for emergency use."[4] FDA has chosen to enforce this law selectively; individuals bringing limited personal supplies of prescription medication into the United States have not been prosecuted. According to a Defendants' Motion to Dismiss in *Andrews v. HHS and FDA,* "the government has not brought, and is not threatening to bring, a single criminal or civil judicial enforcement action against a consumer who has purchased drugs from Canada for personal use, by mail order or otherwise."[5] It should be noted, however, that mixed messages have been sent, and that a policy of selective enforcement does not mean that the agency does not intend to interfere with personal importation. According to a *Chicago Tribune* article from October 21, 2003, an FDA official noted that if the Canadian-based Internet pharmacy CanaRx did not stop shipping drugs to Americans, FDA might order the U.S. Customs Service to seize shipments at the border,[6] and on October 22, 2003, a busload of senior citizens returning from a prescription drug-buying trip to Canada was stopped and searched by FDA inspectors.[7]

But safely insulated by the 1987 law from large-scale, regulated reimportation, which would pose a real threat to industry profits, pharmaceutical manufacturers continued to increase their prices. In 2001, the average cost of a prescription drug was $71.18, an increase of 9 percent from 2000, and an increase of 162 percent from 1990.[8] The percent change in the average price of a prescription from 2002 to 2003 was 9.5 percent (10.2 percent in Illinois).[9] Yet in Canada, where a federal regulatory board sets the price of brand-name medications, the cost of prescription drugs remained approximately between 25 and 50 percent lower than their cost in the United States.

Faced with ever-increasing prices, U.S. residents—especially seniors' groups—began coordinating their efforts to obtain low-cost medication. Organized prescription drug-buying bus trips to Mexico began in the early 1990s. In 1995, the Minnesota Senior Federation started sponsoring trips to Canada. In Vermont and Maine, the buses took off in the late 1990s. Elected officials such as Congressman Bernie Sanders (I-VT), Senator

[3] FDA, Import Alert IA6001, February 24, 1987.
[4] Department of Health & Human Services letter re: Prescription Drug Marketing Act of 1987, August 1, 1988, Docket No. 88N-258L.
[5] Defendants' Motion to Dismiss, *Andrews v. HHS and FDA,* Case No. 1:04CV00307 (JR), June 3, 2004.
[6] Mike Dorning, "Drugs from Canada Spark Debate, Interest Across the U.S.," *Chicago Tribune,* October 21, 2003.
[7] Associated Press report, "FDA Stops Bus Full Of Seniors," April 22, 2004.
[8] Kaiser Network, "Prescription Drugs: Facts at a Glance," Issue Spotlight, kaisernetwork.org.
[9] Kaiser Family Foundation, State Health Facts Online, "Providers and Service Use," http://www.statehealthfacts.org.

Debbie Stabenow (D-MI), and Senator Mark Dayton (D-MN), sensitive to the financial struggles of their constituents, stepped in to help with the funding and organization. It was estimated that in 2001, between 25 and 40 percent of the U.S. residents who traveled to Mexico returned with prescription drugs.[10]

The explosion of the Internet into the daily lives of Americans presented a new opportunity for those in need of affordable medications. Now, Americans who could not afford to buy the drugs their doctors prescribed no longer had to physically travel to another country: they could order the needed medication right from their living rooms. The first Canadian Internet pharmacy—ADV-Care of Ontario—set up its portal in 2000. Others quickly followed suit, and growing numbers of Americans began to use their services. In 2003, the Canadian Internet pharmacy industry achieved revenues of roughly $800 million.[11] A March 2004 Harris poll estimated that six million Americans have purchased prescription medication online.[12] With so many Americans purchasing prescription drugs over the Internet, and with that purchasing trend expected to continue, the government could demonstrate its commitment to protecting the health of millions of citizens by approving regulated reimportation from vetted foreign sources.

House Support for Reimportation and the Pharmaceutical Industry Reply

On July 25, 2003—in acknowledgment of the overwhelming support of their constituents for prescription drug reimportation—members of the United States House of Representatives voted for H.R. 2427 (the Gutknecht-Emerson Bill, co-sponsored by Representative Rahm Emanuel [D-IL]) by a 243-to-186 vote. (See Appendix 3 for a list of all bill cosponsors.) The Pharmaceutical Market Access Act of 2003 would require the Department of Health and Human Services to permit the importation of prescription drugs by pharmacists, wholesalers, and individuals from a predetermined list of 25 countries. The Congressional Budget Office (CBO) estimates that implementation of the Act would reduce total spending on prescription drugs in the United States by $40 billion from 2004 to 2013, and reduce federal spending by $2.9 billion during the same period.[13] The CBO summary reports that the $2.9 billion dollar savings in federal spending would be realized in Medicaid, the Federal Employees Health Benefits program, TriCare for Life, and Medicare Part B, thus passing along a considerable savings to U.S. taxpayers.

In immediate response to the passage of HR 2427, PhRMA—the Pharmaceutical Research and Manufacturers Association—released the following statement:

> …[T]he Gutknecht importation bill is dangerous legislation that jeopardizes the safety of our nation's medicine supply and imports foreign governments' price controls…It is unfortunate that the House did not heed

[10] Markian Hawryluk, "Drugs Without Borders: When Prescription Drugs Go Over the Line," amednews.com, October 22, 2001.
[11] Roger Parloff, "The New Drug War," *Fortune Magazine,* March 8, 2004.
[12] Harris Interactive Poll, January 2004, as reported by PRNewswire, "Six Million People Have Bought Prescription Drugs Online; Most Are Satisfied," March 23, 2004, http://www.biz.yahoo.com/prnews/040323/nytu158_1.html.
[13] Congressional Budget Office Cost Estimate, "H.R. 2427: The Pharmaceutical Market Access Act of 2003," November 19, 2003.

> the repeated warnings of the FDA or the more than 200 patient, physician, pharmacy, and other health organizations that oppose importation of foreign drugs…In addition to passing a Medicare benefit this year, we urge Congress and the Administration to work with us in a sustained effort to overturn foreign governments' price controls on prescription medicines.[14]

A multitude has been enlisted for the "sustained effort" referenced in PhRMA's statement: the pharmaceutical industry has 675 lobbyists on hand to petition members of Congress.[15] As Public Citizen points out, "That's nearly seven lobbyists for each U.S. Senator."[16]

A June 1, 2003 article published in the New York Times provided further information about pharmaceutical lobbying efforts.[17] "Confidential budget documents from the leading pharmaceutical trade group [PhRMA] show that it will spend millions of dollars lobbying Congress and state legislatures, fighting price controls around the world, subsidizing 'like-minded organizations' and paying economists to produce op-ed articles and monographs in response to critics," the article states. "The drug trade group plans to spend $1 million for an 'intellectual echo chamber of economists—a standing network of economists and thought leaders to speak against federal price control regulations through articles and testimony, and to serve as a rapid response team.'" The article also reports that PhRMA's budget allows for an additional $1 million "to change the Canadian health care system."

"Sharing the Burden"

On September 25, 2003, then-Commissioner of FDA Dr. Mark McClellan gave a speech to the First International Colloquium on Generic Medicine in Mexico City. "If we do not find better ways to share the burden of developing new drugs and biologics," he stated, "all of us will suffer…The heart of this problem is that we are not all paying our fair share of the costs of bringing new treatments to the world. And this problem is getting worse. Our governments need to start by sharing the burden of the increasingly complex basic science that goes into the development of new drugs and biologics."[18] McClellan's statement reflected the concerns of the pharmaceutical industry: if Americans are granted access to low-cost, safe prescription medication on a large scale, drug companies will lose money. That money would need to be recouped elsewhere. McClellan also criticized what he termed price controls on drugs in European countries. He repeated these themes to the European Federation for Pharmaceutical Sciences Conference in Basel, Switzerland, on

[14] PhRMA, "House of Representatives Action on HR 2427, the Gutknecht-Emerson Bill," PhRMA.org.
[15] Public Citizen, "2002 Drug Industry Profits: Hefty Pharmaceutical Company Margins Dwarf Other Industries," *Congress Watch,* June 2003.
[16] Ibid.
[17] Robert Pear, "Drug Companies Increase Spending To Lobby Congress And Governments," New York Times, June 30, 2003.
[18] Mark McClellan, speech before First International Colloquium on Generic Medicine, September 25, 2003.

December 8, 2003,[19] and before the Senate Committee on Commerce, Science and Transportation on March 11, 2004.[20]

Yet regulatory bodies in Europe believe that their populations do pay their fair share of research and development costs. The difference in this matter between the EU and the United States lies in the number of people who have prescription drug coverage. In EU countries, where virtually everyone has health insurance and prescription drug coverage, the costs of research and development are spread over that entire population (roughly 454 million in 2004). In the United States, however, one determinant that drug companies use to set prices for medications is based on the drugs' estimated rates of utilization. In Europe, it is understood that virtually all individuals who need a certain drug therapy will receive that drug therapy. In the United States, where 23 percent of the population (67 million Americans) has no prescription drug coverage, that is not a reasonable assumption.[21] Additionally, drug prices in the United States tend to increase year after year (until competitors or generics are introduced) rather than staying the same as they do in the EU. Therefore, the drug-buying population in the U.S. faces constantly increasing prices, further highlighting the difference between the two populations.

The result is not that EU populations are not paying their fair share; rather, it is that U.S. residents who purchase prescription drugs from the U.S. market are paying an inflated price. To further illustrate that EU countries are contributing significantly to research and development (R&D) costs, a 1999 study found that R&D comprised 1.53 percent of total health spending in the UK, France, Japan, Italy, and Canada, while it made up 0.97 percent of total health spending in the United States.[22]

Necessary Costs or an Emphasis on Profit?

The pharmaceutical industry and its supporters have long claimed that higher drug prices in the United States reflect the high costs of research and development, without which new drugs will not be developed,[23] and a recent Tufts University study estimated that the costs to bring a new drug to the market are about $800 million.[24] Yet the independent community watchdog group Public Citizen believes the costs spent on bringing a new drug to market are closer to $240 million. According to the Public Citizen press release,

> [The Tufts Center study] is not representative of real drug industry R&D because none of the 68 drugs used in the Tufts study received any government support…Many, if not most, drugs brought to market receive

[19] Mark McClellan, speech before the European Federation for Pharmaceutical Sciences Conference, December 8, 2003.
[20] Mark McClellan, testimony before the Senate Committee on Commerce, Science and Transportation, March 11, 2004.
[21] Kaiser Family Foundation, "Prescription Drug Trends," May 2003.
[22] Alan Sager and Deborah Socolar, "Affordable Medications for All: Problem, Causes, and Solutions," Access and Affordability Monitoring Project, Boston University School of Public Health, July 1999.
[23] The Heritage Foundation, James Frogue, Executive Memorandum #595, "Why Price Controls on Prescription Drugs Would Harm Seniors," May 1999; ABC News, "Bitter Medicine: Pills, Profit and the Public Health," ABCNews.com, May 29, 2002.
[24] Ceci Connolly, "Price Tag for a New Drug: $802 Million; Findings of Tufts University Study Are Disputed by Several Watchdog Groups," *The Washington Post,* December 1, 2001.

> financial support from the government at some stage in their discovery and development. Therefore, the Tufts study focuses on a skewed sample of drugs and inflates the actual cost of R&D for the average drug…[Also], roughly half of [the study's] estimate ($399 million) is the "opportunity cost of capital"—a theoretical calculation of what R&D expenditures might be worth if they were invested elsewhere. [The study's author] calculated actual out-of-pocket R&D costs for drugs in the study at $403 million per new drug. Those out-of-pocket expenditures are pre-tax costs, however. Drug companies can and do deduct 34 percent of their R&D expenses under federal tax law. Therefore, the actual after-tax cash outlay for each drug in the new Tufts study is about $240 million…But it must be stressed that the average R&D cost for each new drug brought to market is significantly less than $240 million because that figure applies only to the drugs used in the Tufts study [none of which received any government support].[25]

An additional aspect of the pharmaceutical pricing game has been illustrated in a study by the Congressional Budget Office. The study demonstrated that while drug manufacturers sometimes discount the prices of their drugs, they tend to do so only when there are cheaper alternatives on the market. The study found that when a "therapeutically similar" drug is available on the market, the price of the original brand-name drug is discounted. As more competitors enter the market, the discounts for the original brand-name drug increase.[26] Even when discounts are offered, however, they are not offered to all buyers. Rather, they are offered to large bulk purchasers who can negotiate a discount with the manufacturer because of the new threat of competition. Individual or smaller purchasers are often not offered the same discounts. Additionally, a lack of transparency means that savings achieved through a manufacturer discount are not always passed on to the end payer (the individual or the employer). Often, discounts stay with the pharmacy benefits manager or the managed care plan. This illustrates an important point: discounting the price of prescription drugs does not produce the same effect as lowering the price of prescription drugs.

Relief at the Local Level

Despite the pharmaceutical lobby against reimportation, the commitment shown by House members to the provision of safe and affordable prescription drugs reflected a growing trend. Many state and local governments had been working independently to provide their residents with relief for the escalating costs of medication. Illinois officials like Governor Rod Blagojevich and Representative Rahm Emanuel (D-IL) were among the first to officially address the concerns of residents.

---

[25] Public Citizen, "Tufts Drug Study Sample Is Skewed; True Figure of R&D Costs Likely Is 75 Percent Lower," December 4, 2001, http://www.citizen.org.

[26] Congressional Budget Office, "How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry," July 1998.

In Illinois, seniors with incomes of approximately 200 to 240 percent of the federal poverty limit qualify for limited prescription drug coverage through the Pharmaceutical Assistance Program. Also, the Illinois Rx Buying Club (passed unanimously by the Illinois legislature and signed by Governor Blagojevich) has no income restrictions; it has consistently offered seniors and those with disabilities average savings in excess of 20 percent.

Minnesota, Wisconsin, New Hampshire, and North Dakota have included links to Canadian pharmacies on their state websites. In March 2004, New Hampshire Governor Craig Benson used his personal credit card to order prescription medication from a Canadian pharmacy, a move that prompted immediate condemnation by FDA.[27] Legislation regarding reimportation has been passed by three states and the District of Columbia, and as of May 2004, 21 states in all had considered similar measures for their own residents.[28] City governments also have realized the importance of helping residents find low-cost, safe prescription medication. Programs to help city employees and retirees obtain safe, low-cost prescription drugs from Canada have been implemented by Springfield, Massachusetts; San Francisco, California; and Montgomery, Alabama.

Illinois's Canadian Report

On October 27, 2003, Governor Rod Blagojevich released the *Report On Feasibility Of Employees and Retirees Safely and Effectively Purchasing Prescription Drugs from Canadian Pharmacies.* The report, prepared by Illinois's Office of the Special Advocates for Prescription Drugs and a team of specialists, found that pharmacy practice in the Canadian provinces of Manitoba and Ontario was equal or superior to pharmacy practice in the State of Illinois. Canadian methods of ensuring the safety and efficacy of prescription drugs were determined to be comparable to those of the United States. The team concluded that at virtually every level, the United States and Canada had comparable requirements for the warehousing and storage of pharmaceuticals. In fact, the educational requirements and professional regulation of licensed pharmacists in Manitoba and Ontario were as rigorous as those of Illinois; pharmaceutical manufacturing, storage, distribution, and dispensing requirements under Canadian law were substantially equivalent to those required by U.S. federal law; and Illinois pharmacists participating in the fact-finding team observed that incident reporting of internal process errors was more rigorous in Manitoba and Ontario than in the State of Illinois. Furthermore, the team concluded that Canada's system for the pricing and distribution of prescription drugs is less likely to foster drug counterfeiting than the U.S. system.

The team also predicted substantial savings through participation in a Canadian reimportation plan. The State of Illinois administers two major health care programs for

[27] Kaisernetwork.org, Daily Health Policy Report, "New Hampshire Governor Receives Warning from FDA over Prescription Drug Reimportation," April 1, 2004.
[28] John A. Hurson, National Conference of State Legislators, Statement before the Task Force on Drug Reimportation, May 5, 2004.

employees and retirees. Approximately 50 percent of the State's employees and retirees are enrolled in the Quality Care Health Plan (QCHP) administered by Caremark, Inc.; the remaining 50 percent are enrolled in one of nine managed care plans administered by seven separate companies. The maximum, twelve-month savings for the QCHP was projected to be $55 million: $20.7 million would be realized by plan members in the form of waived co-payments, and $34.3 million would be realized by the State through lower overall drug costs.[29] The maximum, twelve-month savings for the managed care plan was projected to be $35.7 million for employees, retirees, and the State of Illinois.[30]

After rigorous analysis and review, the team determined that employees and retirees of the State of Illinois could safely obtain prescription medication from Canada and that the State could reduce its costs and extend the purchasing power of its employees and retirees by implementing a Canadian prescription drug purchasing program.

The Report On Feasibility Of Employees and Retirees Safely and Effectively Purchasing Prescription Drugs from Canadian Pharmacies can be found in Appendix 2.

Reaction from the Pharmaceutical Industry

In January 2003, GlaxoSmithKline announced that it would no longer supply its drugs to Canadian businesses that resell them to U.S. residents. In April 2003, AstraZeneca instituted an allotment program that limits supplies to Canada. In August 2003, Pfizer announced that it would not continue to supply Canadian pharmacies that sell prescription drugs to Americans. And in October 2003, Eli Lilly informed Canadian pharmacies that it would only supply the amount of drugs that Lilly believes is sufficient for Canadian citizens. In all, nine pharmaceutical companies took steps to limit drug supplies to Canadian pharmacies that sell prescription drugs to Americans. In response, the State of Minnesota filed a lawsuit against GlaxoSmithKline in an attempt to force the company to release records that would demonstrate whether or not it violated anti-trust laws when it stopped supplying drugs to Canadian pharmacies that sell to Americans.[31] (More recently, on May 19, 2004, the Minnesota Senior Federation filed a nationwide, class-action lawsuit, alleging that drug manufacturers such as Pfizer and GlaxoSmithKline have violated anti-trust laws by shutting down supply to Canadian pharmacies;[32] and on June 10, 2004, United Senior Action of Indiana filed suit against Eli Lilly and other drug manufacturers for threatening to limit or cut off drug supplies to Canada.[33])

[29] This projection assumed that all eligible prescriptions would be filled by approved Canadian pharmacies. Variables included the currency exchange rate, manufacturer price increases, and the level of employee/retiree participation.
[30] This projection assumed that all eligible prescriptions would be filled by approved Canadian pharmacies. Variables included the currency exchange rate, manufacturer price increases, and the level of employee/retiree participation.
[31] State of Minnesota, Office of the Attorney General, press release, "Hatch Takes Dual Action on Pharmaceutical Industry Front," September 30, 2003.
[32] PharmaLive, "Minnesota Senior Federation, Consumers of Prescription Drugs File Class Action in Response to Drug Companies' Crackdown on Competition from Canada," May 20, 2004, http://www.pharmalive.com.
[33] Norm Heikens, "Indiana Group Joins Rx Drug War," The Indianapolis Star, June 11, 2004, http://www.indystar.com.

In December 2003, an executive briefing from *In Vivo*[34] addressed the pharmaceutical industry's growing concerns regarding the escalating momentum for reimportation. In a brief entitled "Concerning Canada," the authors made it clear that the industry would go to great lengths to prevent the reimportation movement from gaining further support:

> It's possible that the U.S. Food and Drug Administration, which bears responsibility for protecting the health of U.S. citizens, but does not have the authority nor the resources to assure the safety of drugs shipped into this country from elsewhere, will bring suit against states that violate federal law. But short of waiting for the government and regulators to take action, what should the industry do? *IN VIVO* spoke with a range of individuals and agencies, to get a sense of how pharmaceutical and biotechnology companies can and should respond to the ongoing drug re-importation issue. Options include: emphasizing safety concerns; limiting product shipments into Canada; getting tougher in pricing negotiations with countries that impose cost controls; making drug pricing a trade issue; taking more control of distribution; fighting counterfeiting with technology; and playing legal hardball. Companies shouldn't bother comforting themselves with the thought that re-importation is a crime. Laws don't stop criminals—and apparently, federal laws are not stopping state governors and town and city mayors from moving ahead with plans to capture cost savings by facilitating pharmaceutical purchases from Canada. If the pharmaceutical industry cannot establish reasonable doubt that there is nothing different about the medicines being brought into the U.S. from beyond its borders except the price, then the advocates of drug re-importation will get their way.[35]

The pharmaceutical industry employed the majority of these tactics almost immediately. But their attempts to disparage the safety of prescription medication purchased in Canada were rebutted by the Canadian government. According to Diane Gorman, Canada's Assistant Deputy Minister of Health, "Canada's safety record is second to none internationally."[36] Millions of Canadians safely consume millions of prescription drugs each year. PhRMA's anti-reimportation position demonstrates inadequate commitment to helping seniors and other U.S. residents who must find a source of safe, affordable prescription drugs in order to comply with their doctor-ordered pharmaceutical treatment regimens. While several pharmaceutical companies have developed discount cards, they are restricted to low-income seniors and are of no help to the millions of other Americans who cannot afford the high prices of prescription drugs.

[34] A monthly publication by Windhover, a company self-described as "providing superior analysis and commentary on health care business strategy, industry dealmaking, marketplace trends, and the world of medical start-ups," http://www.windhover.com.
[35] In Vivo, The Business & Medicine Review, "Concerning Canada," December 1, 2003.
[36] BenefitNews.com, "U.S., Canada, Join Forces to Regulate Cross-Border Rx Sales," November 20, 2003.

In April 2004, FDA released its own campaign, this one targeted directly at consumers. "Looks can be deceiving," FDA's flyer reads. "The medicine you buy across the borders may be unsafe or ineffective. Don't risk your health."[37] John Taylor, Associate Commissioner for Regulatory Affairs at FDA, expressed that agency's concerns more concretely while testifying before the Senate Committee on Health, Education, Labor and Pensions on May 20, 2004.[38] He spoke about unsafe, ineffective drugs; increasingly larger supplies of domestically counterfeited drugs; inadequately regulated foreign Internet sites; increasing numbers of illegally imported mail-order drugs; improperly licensed foreign pharmacies; and the potential for adverse drug reactions. FDA is right to be thinking of safety—and the current model of unregulated purchasing does prompt concerns about the quality of medicines that are received from substandard sources—but these worries should provide an impetus for the development of a regulated system that does protect the millions of Americans who are already purchasing their prescription drugs outside U.S. borders, and should not be used as an opportunity to punish residents who cannot afford medication at current U.S. prices.

Interestingly enough, the warnings from the pharmaceutical companies and FDA fail to mention some extremely important facts: two of the top five revenue-earning pharmaceutical companies (GlaxoSmithKline and AstraZeneca) are headquartered abroad, and some of the world's most commonly used medications are already manufactured outside of U.S. borders and then imported into the United States for distribution. The pharmaceutical industry cannot have it both ways: either there are safe manufacturing facilities located outside the United States or there are not.

The Medicare Modernization Act and its Limitations

On December 8, 2003, the Medicare Prescription Drug, Improvement and Modernization Act (Medicare Modernization Act) was signed into law. Drug companies, with support from HMOs, pharmaceutical trade associations, and pharmaceutical advocacy groups, had spent millions of dollars (in 2003, they employed 952 lobbyists[39]) defending their claim that a drug benefit in the Act would be the only solution to the problem of supplying affordable, safe, and effective prescription medications to seniors. However, the benefit will not be a comprehensive solution for those who need it most. Faced with the Act's current provisions, residents of the United States will continue to import low-cost prescription medication whether or not it is legal to do so.

When the Medicare prescription drug benefit begins in 2006, beneficiaries will be required to pay a monthly premium of $35 ($420 per year). In addition to the premium, they must pay a deductible of $250 before any level of prescription drug coverage begins. After the premium has been paid and the deductible met, the benefit will require a set of

[37] Food and Drug Administration, "Looks Can Be Deceiving," http://www.fda.gov/bbs/topics/news/2004/NEW01053.html.
[38] John Taylor, statement before the Senate Committee on Health, Education, Labor and Pensions, May 20, 2004, http://www.fda.gov.
[39] Public Citizen, "The Medicare Drug War: An Army of Nearly 1,000 Lobbyists Pushes a Medicare Law that Puts Drug Company and HMO Profits Ahead of Patients and Taxpayers," Congress Watch, June 2004, http://www.citizen.org.

co-payments: beneficiaries will pay 25 percent of charges up to $2,250, 100 percent of charges up to $3,600, and 5 percent of charges over $3,600.[40] The co-payments, as well as the complete lack of coverage encountered at mid-level prescription charges, will provide further incentives for Medicare beneficiaries to continue to seek low-cost prescription drugs elsewhere. To add to seniors' financial stress, co-payments—and the point at which catastrophic coverage begins—will start to rise in 2006 along with inflation rates and Medicare spending rates.[41]

The Medicare drug benefit could have been made infinitely more viable had the Act given the program the right to negotiate drug prices with pharmaceutical companies. The Department of Veterans Affairs, for example, uses its size as a leverage to obtain prescription medication at lower prices for its beneficiaries. In that way, the department fulfills its obligation to taxpayers to provide high-quality services in the most cost-efficient manner possible. The Act, however, explicitly prohibits Medicare from using its purchasing power to leverage low prices for prescription drugs. Each working American subsidizes Medicare benefits; therefore, U.S. workers will foot the bill for non-negotiated prescription drug prices. The salient point is that the benefit will not provide substantial relief for all beneficiaries; they will therefore have continued incentives to purchase lower-cost medication from abroad.

The Medicare Modernization Act did, however, include a directive to study the reimportation question. A task force was formed in early 2004, and is currently chaired by Vice Admiral Richard Carmona, Surgeon General for the United States Public Health Service. Consumer advocates, industry leaders, and physicians and pharmacists have been invited to testify regarding the safety and feasibility of reimportation. On April 14, 2004, Ram Kamath, Pharm.D., and Scott McKibbin—Governor Blagojevich's Special Advocates for Prescription Drugs—testified before the HHS Importation Task Force. They repeated the Governor's message that the State of Illinois must find a way to provide its residents with safe, affordable prescription drugs. Kamath and McKibbin also reiterated the findings of the Governor's Canadian report: that the importation of prescription drugs from Canada is both safe and cost-efficient.

The Link between Rising Drug Costs and Declining Health Outcomes

Despite increasingly vocal cries for help from Americans struggling through an economic recession and facing the loss of 2.35 million payroll jobs since March 2001,[42] pharmaceutical companies maintained—and in many cases actually increased—the price (and profits) of their products. A 2004 study by consumer advocacy group Families USA shared these findings:

[40] Families USA, "The New Medicare Drug Benefit: How Much Will You Pay?", Spring 2004.
[41] Ibid.
[42] CBS News, "Out of Work, Out of Sight," December 29, 2003, http://CBSNews.com.

> The prices of the 30 brand-name drugs most frequently used by the elderly rose by 4.3 times the rate of inflation in 2003. On average, the cost of these 30 heavily prescribed drugs increased by 6.5 percent from January 2003 to January 2004, while the rate of inflation, excluding energy, was 1.5 percent during that same period...Among the 30 brand-name drugs most frequently used by seniors, 14 increased in price by more than five times the rate of inflation from January 2003 to January 2004. Combivent, marketed by Boehringer Ingelheim and used to treat chronic asthma and other serious respiratory conditions, increased in price by 13.2 times the rate of inflation. Alphagan P, marketed by Allergan to treat glaucoma, and Evista, an osteoporosis treatment marketed by Eli Lilly, each increased in price by 10.3 times the rate of inflation. Diovan, used to treat high blood pressure and marketed by Novartis, increased in price by 8.6 times the rate of inflation.[43]

Health plans often have no choice but to increase co-payments and premiums in an attempt to contain these spiraling prescription drug costs. But information linking high prescription drug costs and lack of adherence to prescribed drug treatment regimens has been available since at least 2001,[44] and several recent studies produced by such respected institutions as the University of Michigan, RAND, and the Cleveland Clinic further support these conclusions. According to a press release from the University of Michigan Health System, "nearly half of patients who have a prescription for any of the cholesterol-fighting drugs called statins fail to fill their prescription often enough—or stop filling it altogether, even though statins give the most benefit if used long-term. Not surprisingly, patients' out-of-pocket costs for these drugs are a contributing factor. Patients whose insurance plans make them pay more than $20 for each month's supply are three times more likely to fall behind on their prescription, and four times more likely to stop taking the drug altogether, than those whose co-pay is under $10."[45]

The RAND study found that "when copays doubled, use of prescription drugs fell between 17% and 23% among patients with diabetes, asthma and gastric acid disease. At the same time, ED [emergency department] visits rose 17% and hospital stays increased 10% for the same patients."[46] The University of Michigan Health System further found that "Nearly one in five older adults with diabetes in the survey reported cutting back on prescription medication in the prior year because of costs, and 15 percent used less of their medication at least once per month because of the cost. By not taking their medications as prescribed, patients had poorer diabetes control, more symptoms and

[43] Families USA, "Sticker Shock: Rising Prescription Drug Prices for Seniors," Families USA Publication No. 04-103, 2004.
[44] Center for the Advancement of Health, "Many Seniors Forced to Skip Prescription Meds Because of Cost," December 4, 2001, http://www.hbns.org/newsrelease/prescription12-04-01.cfm.
[45] University of Michigan Health System, "Study: The higher the co-pay, the lower the chance that heart patients stay on cholesterol-lowering drugs," June 8, 2004.
[46] Kaiser Daily Health Policy Report, "Increases in Prescription Drug Copayments Could Decrease Individuals' Use of Necessary Medications, Study Indicates," kaisernetwork.org, May 19, 2004.

worse physical and mental functioning."[47] A February 2004 study by *Diabetes Care* reported, "A total of 19% of respondents [in the survey] reported cutting back on medication use in the prior year due to cost, 11% reported cutting back on their diabetes medications, and 7% reported cutting back on their diabetes medications at least once per month. Moreover, 28% reported forgoing food or other essentials to pay medications costs, 14% increased their credit card debt, and 10% borrowed money from family or friends to pay for their prescriptions."[48]

A March 2004 *Wall Street Journal* article, reporting on the Families USA study, noted that since 2001, the prices of some common drugs used by senior citizens have risen by as much as 25 percent. Pat Kelly, president of U.S. pharmaceuticals at Pfizer, responded in an April 7 letter to *The Journal's* editor that many of Pfizer's drugs are "priced lower than their branded competitors in their class." That may be true; however, the fact that Pfizer's prices are lower than the prices of their branded competitors is not the important point. The essential—and undisputed—point is that the costs of some drugs commonly used by senior citizens have risen by as much as 25 percent since 2001.

But despite the availability of information linking high drug prices to poor health outcomes, shareholders at Pfizer—which reported $45.2 billion in revenues in 2003[49]—voted not to "limit Pfizer's price increases to the rate of inflation"[50] during their April 2004 meeting.

Prescription Drugs and Health Insurance

On April 8, 2004, the Illinois Attorney General filed a citizen's petition with FDA in an attempt to force the agency to respond to Governor Blagojevich's December 2003 request to establish a drug reimportation pilot program in the State of Illinois. On April 20, the Governor directed his Office of the Special Advocates for Prescription Drugs to study the European prescription drug distribution system to determine whether Illinois residents and businesses could safely and cost-effectively obtain prescription drugs from Europe. "[A]t least five [major drug companies] have decided to limit the supply of drugs they sell to Canadian pharmacies, to deprive Americans of access to lower-priced medications," said Blagojevich. "What that tells me is we cannot limit our search for lower-priced prescription drugs only to Canada. As the old saying goes, there's a big world out there. A world in which the people of every industrialized country pay far less for prescription drugs than we do here in the United States."

Residents of industrialized European nations pay far less for prescription drugs—and far less for health care costs in general—than do Americans. Yet even though Americans pay

[47] University of Michigan Health System Press Release, "Study: Diabetes Patients Skip Medications to Save Money," February 12, 2004.
[48] John D. Piette et al., "Problems Paying Out-of-Pocket Medication Costs Among Older Adults With Diabetes, *Diabetes Care 27:384-391,* February 2004.
[49] AARP, "Rx Watchdog Report," Summer 2004.
[50] Ceci Connolly, "A Small Win for Proponents of Drug Importation," *The Washington Post,* April 23, 2004.

more for their health care, citizens of Belgium, France, Germany, the Netherlands, and the United Kingdom enjoy lower infant mortality rates and greater life expectancy rates.[51] European employers and workers are for the most part required to contribute to their country's health care systems. There are few opt-out options: virtually all Europeans are covered. Some European countries require co-payments, but these are typically low, often are capped by the government or reimbursed, and are not applied to certain, vulnerable populations.[52]

Roughly 85 percent of Americans have some type of health insurance coverage, but health insurance in the United States is far from consistent. Insured Americans face different premiums, co-payments, deductibles, formularies, and covered services. High premiums, deductibles, and co-payments can quickly replicate conditions of non-insurance: if an individual is insured but cannot afford his co-payments or premiums, then he effectively has no health insurance at all.

In the United States, private insurance can be obtained through an employer or purchased directly by an individual. Employer-sponsored insurance is more affordable, as employers subsidize a portion of an employee's coverage. Also, employers are able to negotiate better prices for health insurance coverage: because they are buying the product (in this case, health insurance) in bulk, they can negotiate discounts from health insurance providers. Even so, employer-sponsored health insurance does not necessarily include prescription drug coverage. In 2000, 8 percent of individuals with employer-sponsored insurance coverage did not obtain a prescription drug because of cost.[53]

Individuals who purchase health insurance on the open market face a much different situation. Because individuals may not be part of a plan comprised of a large number of members, in which financial and health risks are pooled, they pay a much higher price. Additionally, individuals pay for the entire cost of their insurance without the help of an employer subsidy. In the United States, employer-sponsored insurance is also, in a sense, subsidized by the government: money paid by employers and employees for health insurance coverage is taken from pre-tax dollars. Many individual purchasers do not enjoy this benefit. [54]

Public, or government-sponsored, insurance in the United States also takes many forms. One type of public insurance is available to members of the military. A second type, Medicare, is an entitlement program available to Americans over the age of 65 (and also to individuals with end-stage renal disease). Medicare provides comprehensive hospital services, more limited physician services, and, currently, no prescription drug coverage.

---

[51] World Health Organization, "Core Health Indicators," 2000, http://www3.who.int/whosis/core/core1.cfm?path=whosis,core_indicators&language=english.
[52] European Observatory on Health Care Systems, "The Western European Experience with Health Care Reform," April 2002.
[53] Center for Studying Health System Change, "Affording Prescription Drugs: Not Just a Problem for the Elderly," April 2002, http://www.hschange.com.
[54] Katie Merrell, "When Worlds Collide: Public Policy, Private Markets, and the Price of Health Insurance," in *Covering America: Real Remedies for the Uninsured,* available online at the Economic & Social Research Institute, http://www.esresearch.org, 2001.

A third kind of public insurance, Medicaid, is a program available to a portion of low-income Americans. However, a 1999 study reported that 26 percent of Medicaid recipients between the ages of 18 and 64 could not afford to fill a prescription in the previous year.[55]

Regardless of which type of insurance an individual has, the costs of that insurance—and the services offered—are likely to be extremely dissimilar. This leads to a great disparity in overall access to health care and levels of prescription drug coverage.

In the United States, 38 percent of Medicare beneficiaries (15 million seniors) have no prescription drug coverage,[56] 23 percent of the U.S. population (67 million Americans) has no prescription drug coverage,[57] and 500,000 senior citizens lack prescription drug coverage in Illinois alone.

According to a study released by the Kaiser Family Foundation in September 2000, 15 percent of uninsured children had gone without prescription medication in the previous year because of cost, 28 percent of uninsured adults went without prescription medication because of cost, and 87 percent of uninsured individuals with serious health problems reported trouble obtaining needed medication.[58] Christina Zamora, interviewed for the study, remarked "I find myself in a very bad situation, and it's scary. I can't afford several of my medications. I take two types of hormones, and they cost $48. And my high blood pressure medicine costs $8 a bottle. So, I have to make a choice. I just don't take the hormones."[59] Dianna Oden, who suffers from chronic pain, reported similar frustrations: "When the pharmacist filled [the prescription], he told me it would cost $149. I told him, 'I can't afford to buy them all,' and he asked me, 'How many can you afford?' I said, 'Six,' so that's what he gave me."[60] A mother with young children recalled that she could not afford the prescription medication needed to treat her daughters' chronic bronchitis: she substituted saline solution for the prescription Albuterol in their nebulizers.[61]

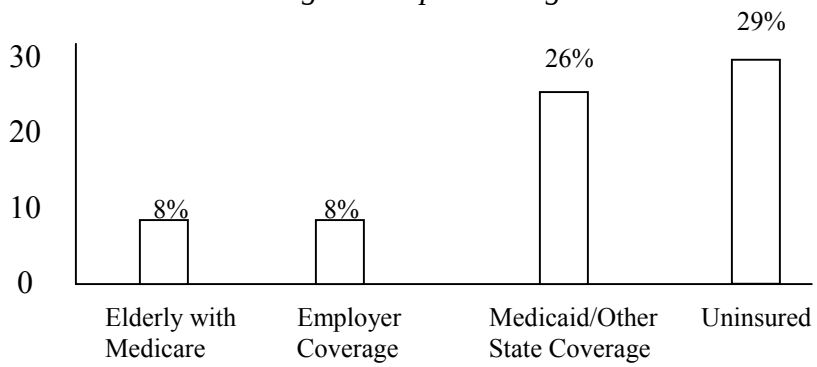
Illinoisans without prescription drug coverage come from many different walks of life. Workers, students, seniors, children, and men and women of varying income levels all make up the statistics and numbers seen on the news. For example, Ben Turner—a 52-year-old repair technician from Chicago—faces prescription drugs bills of $700 each month. "I have to make a choice between eating and medicating myself," he states.[62] And consider Ray and Gaylee Andrews of Elk Grove Village. After a lifetime of work and frugal living, Ray and Gaylee thought they could retire and enjoy some well-deserved rest. Yet they soon found that they were faced with a harsh choice: they would either need

[55] America's Second Harvest, "Issue Paper 1: Choices—Medical Care or Food?", 2001, http://www.secondharvest.org.
[56] Kaiser Family Foundation, "Prescription Drug Trends," May 2003.
[57] Ibid.
[58] Kaiser Family Foundation, "In Their Own Words: The uninsured talk about living without health insurance," September 2000, http://www.kff.org.
[59] Ibid.
[60] Ibid.
[61] Ibid.
[62] T. Shawn Taylor, "Extend Jobless Benefits, Illinois Democrats Urge," *The Chicago Tribune,* April 20, 2004.

to forego the necessary, life-maintaining prescription medications that cost them almost $1000 every month, or they would have to continue to work in order to pay for the drugs their doctor prescribed. Today, Ray and Gaylee—both 74—between them work three part-time jobs to pay for their medication.[63]

The following graph, containing information from the Center for Studying Health System Change, shows the percentage of Americans who did not obtain at least one prescription medication in 2000–2001 because of cost.

Figure 1
"Percent Not Obtaining Prescription Drug Due to Cost"[64]



Recent Developments

On May 4, 2004, Secretary of Health and Human Services Tommy Thompson surprised the pharmaceutical industry when, according to the Associated Press, he stated that legalizing the reimportation of prescription drugs was inevitable and would save consumers money.[65] Thompson's remarks gained support on May 5, when chairman and chief executive officer of CVS Thomas Ryan agreed. Testifying before the Drug Reimportation Task Force, Ryan—at the helm of a chain of drugstores that dispense more prescriptions than any other U.S. drugstore chain[66]—stated, "While many in our industry believe that importation is a fundamentally flawed concept and oppose it without exception, I have come to a slightly different view. Simply put, there are too many patients our pharmacists never see because they cannot afford the drugs we dispense, and others who are unable to pay for a full regimen of medications because it soaks up so much of their disposable income."[67]

A spokesman from HHS, however, made it clear that Thompson's statement reflected a personal opinion only, and that the administration had not reconsidered its anti-

[63] CNN, "Retirement: Ready or not, here it comes!", http://www.cnnmoney.com, May 15, 2002.
[64] Center for Studying Health System Change, Issue Brief #51, "Prescription Drug Access: Not Just a Medicare Problem," April 2002, http://www.hschange.com.
[65] Kaisernetwork.org, Daily Health Policy Report, "Bipartisan Prescription Drug Reimportation Legislation Will Likely Pass Congress, Bush Should Not Veto, HHS Secretary Thompson Says," May 5, 2004.
[66] MarketResearch.com, "CVS BusIntell Report," February 1, 2004.
[67] Amanda Gardner, HealthDayNews, "Support for Canadian Drug Imports Hits Groundswell," May 6, 2004.

reimportation policy.[68] On June 4, 2004, HHS formally rejected Governor Blagojevich's petition to start a pilot prescription drug-buying program, rebuffing the Governor's continued attempts to work hand-in-hand with the federal government to bring affordable prescription drugs to Illinois residents.

The debate over drug reimportation—an issue that has forged a remarkable bipartisan coalition—shifted from the House to the Senate in the summer of 2004. Currently, there are three reimportation bills before the Senate: S. 2328, sponsored by Senator Dorgan (D-ND), S. 2493, sponsored by Senator Gregg (R-NH), and S. 2307, sponsored by Senator Grassley (R-IA). All three bills concern the importation of FDA-approved drugs from foreign countries into the United States. Specifically, all three bills address both personal and commercial importation from Canada and consider the eventual importation of drugs from other countries (particularly 2003 European Union members). Each bill also details new monitoring practices to be undertaken by FDA and provides for the charge of reimportation service fees that will cover FDA's new costs.

Of these three choices, the bill that assures patient safety and ease of implementation is S. 2328, the Dorgan-McCain-Kennedy-Snowe bill (for a complete list of the bill's cosponsors, see Appendix 4). This legislation requires registration by and inspection of all entities that will directly distribute to American consumers, and requires complete chain-of-custody documentation regarding the safety of the drug itself. The Dorgan bill also anticipates obstacles that anti-importation forces (such as pharmaceutical manufacturers) may employ to derail implementation. Lastly, the legislation allows FDA to collect the fees necessary to fulfill their new requirements and ensure the continued safety of the drug supply.

While S. 2328 (Dorgan) features many desirable safeguards, its restriction of personal importation to Canada only is troublesome. To successfully provide greater access to lower-cost medications, both personal and parallel importation options should be available from all countries listed in the bill. If a viable personal importation model is not available, or is restricted to a single country, there is less incentive for a parallel importer to pass on savings to the end customer. Additionally, the tri-weekly inspection of participating facilities required by S. 2328 will be costly (in terms of funding and manpower) and possibly unnecessary. Many facilities—for example, the Canadian facilities as determined by the GAO report of June 17[69]—will continue to provide top-quality service without such frequent monitoring. The authors of this report believe that FDA can and should determine appropriate inspection intervals based on its expertise.

Two recent developments regarding the House and Senate bills merit additional comment. First, on June 14, 2004, the House Appropriations Subcommittee on Agriculture, Rural Development, FDA and Related Agencies approved an amendment to

[68] Ibid.
[69] General Accounting Office, "Internet Pharmacies: Some Pose Safety Risks for Consumers," Report to the Chairman, Permanent Subcommittee on Investigations, Committee on Governmental Affairs, U.S. Senate, June 2004.

a bill that would prohibit FDA from spending any money to prevent drug reimportation.[70] Second, on June 16, 2004, the AARP (formerly the American Association of Retired Persons), a non-profit advocacy group with a membership of 36 million Americans, released a statement confirming its endorsement of the Dorgan bill (S. 2328). Bill Novelli, CEO of AARP, stated the following:

> The Medicare Modernization Act is an important foundation, but much more must be done to control the cost of prescription drugs, and to make sure that our members and their families have access to the drugs they need. AARP recently released a study showing that prescription drug prices in 2003 increased at nearly triple the rate of inflation. Americans need affordable prescription drugs now…It is a national embarrassment that citizens must purchase from other countries to afford prescription drugs. It is no longer a question of *whether* we should allow the importation of drugs from abroad. Importation is already happening on a large scale; we must ensure that there is a system in place for guaranteeing safety and cost savings.[71]

Later that month, the accounting firm Ernst & Young released a study regarding the U.S. pharmaceutical industry. Blake Devitt, a senior partner with the firm, stated, "Unless the pharmaceutical industry takes steps within its own ranks to effect an alternative solution, U.S. price controls, reimportation, or both seem inevitable."[72]

Additional Support from Key Players

On June 17, 2004, the General Accounting Office (the federal office tasked with helping Congress make informed fiscal and policy decisions) released a report that supported the findings of Governor Blagojevich's Canadian team. The study concluded that "prescription drugs obtained from Canadian websites pose fewer risks than medications purchased from online pharmacies elsewhere—including the United States. In some instances, Canadian pharmacies were also found to have stricter standards than those in the United States."[73] All 18 Canadian Internet pharmacies tested, for example, required a prescription; only 5 of 29 U.S. Internet pharmacies required a prescription before medications were dispensed and shipped.[74]

On June 18, 2004, Health Canada—the Canadian equivalent of FDA—submitted a report of findings to the Task Force on Drug Importation at the Department of Health and

[70] Kaiser Daily Health Policy Report, "House Agriculture Sub-panel Approves Bill That Would Prevent FDA From Enforcing Prescription Drug Reimportation Ban," June 15, 2004, http://www.kaisernetwork.org.
[71] Bill Novelli, "Statement in Support of Rx Drug Importation Legislation," June 16, 2004, http://www.aarp.org.
[72] Reuters News, "Ernst & Young Says U.S. Drug Price Controls Likely," June 23, 2004, http://www.reuters.com.
[73] AP report, "Probe: Canada Drugs Safer," *The Miami Herald,* June 17, 2004, http://www.miami.com.
[74] General Accounting Office, "Internet Pharmacies: Some Pose Safety Risks for Consumers," Report to the Chairman, Permanent Subcommittee on Investigations, Committee on Governmental Affairs, U.S. Senate, June 2004.

Human Services. Diane Gorman, Assistant Deputy Minister at Health Canada, stated the following:

> Health Canada has a rigorous system for the regulation of therapeutic products comprised of three main components: pre-market review to determine if the product meets the legislative and regulatory requirements; post-market surveillance to monitor the safety and therapeutic effectiveness of the product; and inspection to verify compliance with the Food and Drugs Act and its Regulations. Drugs imported for sale in Canada, or for subsequent export, must first be approved by Health Canada and meet the requirements of Canada's Food and Drugs Act and Regulations. Through these activities, Health Canada ensures the products intended for Canadians are safe, efficacious and of high quality…
>
> Health Canada's Health Products and Food Branch has an Inspectorate which is tasked with verifying compliance with the Food and Drugs Act and Regulations and, where necessary, taking steps to enforce the prohibitions outlined in these laws. Pursuant to their authority under the Food and Drugs Act, inspectors can enter and inspect places where therapeutic products are manufactured, prepared, preserved, packaged or stored in order to verify/monitor that Canada's food and drug laws are being complied with. If any non-compliance with federal laws is found, appropriate compliance and enforcement actions are taken…
>
> The regulation of drug safety worldwide is based on the premise that each country is responsible for the safety of products made available to its citizens. Health Canada contributes to maintaining and improving the health of Canadians by ensuring that drugs and other therapeutic products sold in Canada are safe, of high quality and therapeutically effective in accordance with their labeling, and with partners and stakeholders, are appropriately used and accessible in a timely and cost-effective fashion.[75]

Furthering support for reimportation, Thomas Ryan, CEO of CVS Pharmacy, essentially agreed with a fundamental parallel import model in a June 18, 2004, op-ed piece in the *Chicago Tribune:*

> The answer [to the problem of high prescription drug prices] is for the pharmaceutical industry to move toward a global pricing model in which prices in different countries are set by the normal economic forces of supply and demand, as they are for virtually every other traded product…

[75] Diane Gorman, "Input from Health Canada to the Public Docket for the United States Department of Health and Human Services," June 18, 2004.

> I propose…bulk importation. In the U.S. we already have a drug distribution system that handles more than 3 billion prescriptions a year safely and effectively, where pharmaceutical manufacturers deliver product to dozens of distributors, who then deliver it to more than 55,000 licensed pharmacies. We don't need a new distribution system. What we need is a way to get safe, unadulterated drugs into the system we have. To do that, we can develop a system to certify specific foreign drug suppliers, probably wholesalers in other countries, who would sell to domestic wholesalers and then on to retail pharmacies…
>
> To deal with this real and pressing need…the Bush administration and Congress should legalize prescription-drug importation…the country needs to face this issue and devise a solution.[76]

What Ryan has recommended is quite similar to one of the recommendations proposed in this report. Before arriving at a proposal, however, a review of the history of the European parallel import model is germane.

Parallel Importation of Prescription Drugs

Prescription drug prices are different in European Union (EU) member countries. As explained by Donald Macarthur, Secretary General of the European Association of Euro-Pharmaceutical Companies, "Willingness and ability to pay, medical practice, demand side management, and even value judgements in healthcare differ between countries, and therefore so do prices."[77] These differentials allow drugs to be purchased in countries where prices are low and resold for a profit in countries where prices are higher. This is parallel import in its simplest form.[78]

Parallel import, which has been occurring since the mid-1970s, is based upon the free movement of goods between European Union member states. The statutory foundation for parallel import is found in the Treaty of Rome: Article 81 prohibits the prevention of competition that may affect trade between member states, while Article 82 prohibits dominant markets from abusing their positions to affect trade between member states.

Many EU countries actively encourage parallel importation because of the cost savings it offers to governments. For example, it was traditionally illegal in the UK for any party to a transaction to offer price discounts for prescription drugs. When a pharmacy dispensed prescription medication, the government would pay the pharmacy a standard dispensing fee to reimburse the pharmacist for the cost of dispensing the prescription. However, when wholesalers started offering discounts on parallel-imported medications,

[76] Thomas M. Ryan, "Make prescription drugs affordable," *Chicago Tribune,* June 18, 2004.
[77] Donald Macarthur, "Parallel Trading of Medicines in Europe: The Case for a Fair Deal," adapted from the author's previous work in *Consumer Policy Review* of the UK's Consumer Association, Jan/Feb 2001, volume 11, number 1, 6-10.
[78] It is a common misconception that all European countries employ price controls to keep drug costs low. Pharmaceutical companies often enter into freely negotiated price arrangements with national governments in exchange for the privilege of conducting business.

pharmacies received increased profit margins. The government realized that businesses were earning large profits by offering discounts, and they began to reduce the amounts paid for dispensing through a process known as "clawback." Today, the government recovers a portion of the profit a business would have earned—roughly 10 percent—by offering discounted drugs. The UK government has a financial interest in recommending the purchase of less expensive medication: each time a cheaper (and often parallel imported) drug is dispensed, the government is able to retain a larger portion of the clawback. The government clawback is adjusted every few years.

Not just anyone can declare himself to be a parallel importer. Legally, parallel importers are considered to be manufacturers; as such, they are held to strict standards and are required to maintain scrupulous records. Would-be parallel importers must apply for and obtain a marketing authorization for the country in which they wish to sell the medication. Also, As Macarthur writes, "Wholesalers are naturally obliged to meet orders from local pharmacies first…In fact, in several countries, there is 'public service obligation,' written into law, that requires wholesalers to meet demand from their normal territorial area within a certain time limit."[79] Only the surplus product can therefore be exported by the wholesaler. Additionally, in the UK, any product brought into the country by a parallel importer is required to be the same as the domestically available product (shape or color may be different, but drug ingredients and strengths must be equal). Furthermore, parallel importers must obtain licenses not only to parallel import products but also for each drug from each different country.

Historically, the implications of parallel import were limited to the original fifteen countries of the European Union. But when more countries sought to enter the EU—countries whose economic status implied they would be negotiating drug prices at the lower range of the payment spectrum, thus creating additional opportunities for increased parallel import—pharmaceutical companies grew increasingly concerned about their European profits. They soon achieved several important victories. When ten new countries joined the EU in 2004, their admittance was conditional upon their agreement not to participate in parallel importing with the original member states of the EU until their patent protection laws were judged to be equal to those of the original members (new EU members were assigned a predetermined period of time during which they must become compliant; after that period expires, they are permitted to participate in parallel import). Additionally, all parallel importers in the EU are now required to notify patent holders of their intent to parallel ship products 30 days in advance of applying for shipment. The patent holder can therefore start legal proceedings against the shipper if it believes the intended shipment would violate its patent.

The pharmaceutical industry and its supporters often claim that parallel import and price controls kill research and development.[80] Yet according to a 1999 study by Alan Sager

[79] Donald Macarthur, "Parallel Trading of Medicines in Europe: The Case for a Fair Deal."
[80] Pharmaceutical Research Manufacturers of America, "Gutknecht-Emerson bill Exposes U.S. to Unsafe Foreign Medicines, Cedes Authority to World Government Price Fixers," PhRMA, October 7, 2003,

and Deborah Socolar of the Boston University School of Public Health, U.S. research and development comprised only 0.97 percent of total U.S. health spending while it comprised 1.53 percent of total health spending in the UK, France, Japan, Italy, and Canada.[81] Regardless of the numbers, the pharmaceutical industry continued to use its deep pockets to fight against the strengthening parallel importation industry. But each time a legal challenge was made—25 times between 1974 and 2003—the European Court of Justice ruled to uphold the parallel import model. As the European Commission wrote in the XXVth Report on Competition Policy, "On several occasions the Court of Justice has ruled that parallel imports should not be blocked, irrespective of the factors that determine price differences. Hence, in the pharmaceutical sector, the Commission has correctly applied the competition rules to agreement or conduct which restrict parallel trade in drugs."[82]

The most controversial decision issued by the European Court of Justice (ECJ) was handed down in 1981. The ECJ ruled that if a patent holder placed a product for sale in the market of a European Union member state that did not guarantee patent protection, then the product could also be sold on the markets of all other member states without adherence to patent rules. This was interpreted widely as a move that bolstered the idea of a single market for the European Union. That ruling was upheld in a 1996 court case.

Consistently denied legal headway by the ECJ, pharmaceutical companies looked for new ways to control European markets and protect their high profits. Their solution? Create supply shortages. As Macarthur writes, "Under the guise of 'supply-chain management', there is a growing trend by multinational manufacturers to apply fixed quotas…to the amount of goods they supply to certain of their local subsidiaries. Wholesalers in these countries cannot buy sufficient stock or, in some cases, any stock at all. Quotas freeze market shares of existing wholesalers and deny market access to newcomers, and are therefore by definition anti-competitive…manufacturers have argued that quotas are designed to ensure local needs are fully met, but in practice the consequences may be the very opposite. Shortages of affected products did not exist in Greece until their supplier decided to 'improve' the effectiveness and efficiency of the supply chain, the national regulatory authority (EOF) has verified."[83]

Conclusion

Despite opposition from FDA and significant efforts by the pharmaceutical industry, millions of Americans—desperate to find sources of affordable medications—are importing prescription drugs. Some of these drugs may be adulterated or of poor quality.

---

http://www.phrma.org/publications/policy/admin/10.07.2003.779.cfm; California Healthcare Institute, "The Economics of Innovation: Global Price Controls and the Future of Biomedical R&D," February 19, 2004, http://www.chi.org.

[81] Alan Sager and Deborah Socolar, "Affordable Medications for All: Problem, Causes, and Solutions," Access and Affordability Monitoring Project, Boston University School of Public Health, July 1999.

[82] European Commission, "XXVth Report on Competition Policy," as quoted by Donald Macarthur, "Manufacturers' Counter-strategies to Parallel Trade: Do Any Make Sense?", *Scrip Magazine,* July/August 2002.

[83] Donald Macarthur, "Manufacturers' Counter-strategies to Parallel Trade: Do Any Make Sense?", *Scrip Magazine,* July/August 2002.

Some Internet pharmacies pretending to be based in Canada may actually be located somewhere else. These concerns highlight the problems associated with the current model of unregulated purchasing. However, worries such as these should provide an impetus for the development of a regulated system that does protect the millions of Americans who are already purchasing their prescription drugs outside U.S. borders, and should not be used as a tool to punish residents who cannot afford needed medication at current U.S. prices. The public health officials of the State of Illinois and the United States must work to provide a safe, affordable alternative to the current system. Therefore, we move next to the findings of Illinois's European delegation and a discussion of Illinois's options in pursuit of this report's objective.

III. How Might the State of Illinois Enter the European Pharmaceutical Market?

In April 2004, as FDA had not yet responded to Illinois's invitation to work cooperatively on the issue of reimportation from Canada, Governor Blagojevich asked a small working group (comprised of members of the Governor's office and the Office of the Special Advocates for Prescription Drugs) to turn their attention to Europe. The group had approximately two months to complete its research. The mandate to the group was to explore whether there were other ways to address the prescription drug reimportation issue, since many Canadian Internet sites utilized by U.S. residents (on an individual and state-wide basis) were facing artificially constructed supply shortages created by a number of pharmaceutical manufacturers.

The working group revisited the policy analytic framework used to develop the central and key issues for the Canadian report, and developed criteria and formulated hypothetical alternatives that might result from focused European research. This exercise was used to construct a highly focused research plan for the needed information and to identify potential sources and stakeholders from which to develop that information. The effort was intended to make the information gathered by the European delegation as condensed and effective as possible, and to ensure that the role and scope of each delegation member's inquiry were known and prepared.

The working group expanded its investigation beyond the initial study's focus on the feasibility of the State's own employees, retirees, and dependents safely and cost-effectively accessing brand-name maintenance prescription drugs through the Canadian Internet pharmacies. For the European study, the central policy issue to be addressed was, *Can Illinois residents and businesses safely and effectively obtain prescription medication at lower overall cost by purchasing prescription medications from Europe?* The delegation understood that any questions they developed might apply to both models they intended to study:

1) Personal importation of brand-name maintenance pharmaceuticals as addressed in the Canadian study, and

2) Wholesale importation of drugs into standard pharmacy distribution, enabling importation of a wider variety of drug classes.

Safety concerns were paramount. The delegation knew it would need to probe the practice of pharmacy in Europe. Was it as regulated as it is in the U.S. and Canada? Were standards and practices also comparable for manufacturing, warehousing, and storage? Could dispensing of brand name, maintenance prescription medications from Europe be as safe or safer than conditions found in Illinois? Would counterfeiting present real concerns and obstacles, or would it be a non-issue?

Structure and feasibility issues were also addressed. Could logistical issues—such as dispensing policies, language, time zones, and transportation expenses—be overcome, and would it be practical to do so? Could European pharmaceuticals be imported on a wholesale basis? What were the sources of European prescription drugs? Do the same companies provide the same drugs? How are pharmaceuticals approved in Europe? Does the European Union have a counterpart to FDA, and does it function in the same way? What are the natures of the wholesaling and manufacturing industries in Europe, and how are they regulated? How does the European parallel importing policy for pharmaceuticals work, and would there be potential for wholesaling directly to the United States? Are issues such as pharmacy practice, utilization management, and detailing the relationships between government programs, insurance funds, and the pharmaceutical industry managed comparably to the United States or differently?

Questions about costs and pricing arose. Is pharmaceutical pricing more or less transparent in Europe than in the United States? What are the methods of reputed "price controls" in Europe, and how do these relate to Illinois and U.S. policy? Are these real "controls"? What is the relationship of the European community's pricing methodology to research and development?

Other queries also presented themselves. Can the pharmaceutical industry in Europe use patent-extending applications to maintain sales exclusivity and develop "me too" drugs to poach existing markets, or are they required to demonstrate increased value? Could U.S. generic manufacturers (that provide less expensive medications in the U.S.) find new markets abroad in a free-trade model? Could pharmaceutical companies compete in a free-trade economy? How would the European governments, insurance funds, and components of the pharmaceutical industry (manufacturers, wholesalers, pharmacists, and professional associations) regard U.S. importation of European pharmaceuticals?

Criteria were developed to evaluate potential alternatives; these would be applied in the initial exercise of the hypothesized alternatives, and subsequently after the research was developed. The criteria fall broadly into four categories: effectiveness, cost, feasibility, and timing. The criteria would be assessed with a directional measure (a weight) relative to the other alternatives. The detailed sub-criteria and weightings used in the analysis are available in Appendix 13.

Alternatives

The alternatives hypothesized prior to the visit varied along the dimensions of which drugs might be included, which model (personal vs. parallel importation) would be used, and which nations might be considered as sources (the overall number of nations as well as different regions). The options considered in the preliminary exercise, intended to define the necessary research and test the criteria, included the following:

1. All prescription drugs, parallel importation (wholesale), importation only for distribution through U.S. pharmacies.
2. All prescription drugs, parallel importation and exportation, under a competitive free trade model.
3. Brand drugs for maintenance only, parallel importation only.
4. Maintenance drugs, personal importation (both brand and generic), from a restricted list of countries.
5. Maintenance drugs, personal importation, global (but vetted) sources.

Research Plan

The working group developed the new research plan by defining the data and information needed, along with the most likely corresponding sources, in order to complete a fully informed analysis (see Appendix 11). The research plan required meeting with representative experts from European governments, manufacturers, pharmacies, wholesalers, parallel importers, health and insurance funds, and professional and trade associations. The Special Advocates developed an aggressive schedule for meetings in Europe, and the multi-disciplinary team that had visited Canada was largely reassembled to conduct the European visit.

The Delegation

The delegation sent to Europe (see Appendix 5) was comprised of the Governor's office, the Office of the Special Advocates for Prescription Drugs, and policy and technical specialists responsible for the State under the Departments of Public Health and Professional Regulation. The delegation managed to conduct inspections, discussions, and site visits in six countries (Belgium, France, Germany, Ireland, the Netherlands, and the United Kingdom). Governmental meetings were held in Belgium, France, Germany, and the Netherlands with the European Union's counterpart to FDA regarding industry relations, and parallel importers were visited in France, Germany, Ireland, and the United Kingdom. Insurance and sick funds (entities similar to publicly funded, not-for-profit health maintenance organizations in the United States) were visited in Belgium and France. Trade associations were met with in Belgium, France, and the UK. Pharmacies were visited in every nation except for Germany and the Netherlands. Policy documents, studies on parallel importing, and published drug price information were gathered.

The delegation methodically assessed pharmacy practices, pharmaceutical manufacturing, warehousing, storage, and distribution processes and compared these to Illinois standards. Where possible, the delegation developed information on the regulatory processes and standards regarding the safety and efficacy of drugs and pharmacy practices, dispensing and drug costs, research and development concerns, pricing methodologies on a national basis, and methods of managing prescription drug utilization management, including innovative strategies for improving physician understanding of the efficacy of drug substitutions and selections. Significant ideas were developed that may (in subsequent

initiatives beyond the scope of importation) serve as the basis for Illinois and the United States to address and help manage the rising cost of prescription drugs.

This section synthesizes the policy research and practical fieldwork assembled by the delegation. This synthesis provided a context for understanding the options the State of Illinois had to participate and engage in efforts that would assure the safety and efficacy of importing prescription drugs on behalf of its residents and businesses.

Parallel Import Market Structure

A recent study by the York Health Economics Consortium explains the parallel import process and its economic advantages. In the first step, a price is negotiated and agreed upon by the original manufacturer of a drug and the government of European Country A (such as Spain, Greece, or Portugal). A wholesaler then steps in and acts as an intermediary between the manufacturer and the pharmacies of that country. The wholesaler may negotiate a better price than the government. A parallel importer will then purchase drugs at the price offered by the wholesaler of Country A and repackage them for sale in country B (such as the UK, Sweden, or Germany); those drugs are then sold to a wholesaler in Country B, where the drug price negotiated by the government is higher. The wholesaler in Country B can then sell drugs to local pharmacies at lower prices than could have been obtained from Country B's intended supply. The pharmacies of Country B then sell the drugs to the public at a mark-up. Country B's public health plan reimburses its pharmacies at the prices it previously negotiated, regardless of whether a drug has been supplied by parallel import or from the supply originally intended for that country. The savings therefore stay with the pharmacy, which has obtained drugs from a cheaper source in Country A, rather than being passed along to the government of Country B. Consequently, the government of Country B "claws back" some of the difference by reducing the reimbursement rate.[84]

IMS Health (Intercontinental Marketing Services), a global information firm that studies the pharmaceutical industry, reports that parallel importers have recently become more sophisticated.[85] They are "capable of identifying future blockbusters before they are launched, and licenses are much quicker to obtain—resulting in trading firms that today are better financed."[86] Because parallel importers deal directly with wholesalers rather than pharmacies, they can move their stock and receive payment quickly, and therefore have increased influence on the market for a new drug. IMS also points out that while parallel importers have had a hard time competing with generics in the past, today they import and market Prozac even though it is available in generic form: "the price difference needed to continue its importation is much less than the price difference that made importation worthwhile in the first place."[87]

[84] York Health Economics Consortium for the European Association of Euro-Pharmaceutical Companies, "Benefits to Payers and Patients from Parallel Trade," May 2003.
[85] IMS Health, "Parallel Trade: A Global Pharma Worry," http://www.imshealth.com.
[86] Ibid.
[87] Ibid.

A similar parallel import market structure could benefit all participating Illinois pharmacies and wholesalers by granting them access to low-cost prescription medications that they could then sell at a profit. Illinois consumers would also benefit from a parallel import system through access to a wider selection of imported drugs available at their local pharmacy.

Market Impact

Adverse economic impacts have been projected as a result of pharmaceutical importation. These mainly relate to issues of supply and research and development. While heavily contested, both logically and empirically, they need to be considered in the context of assessing the feasibility of an Illinois initiative and framing a recommendation.

The most immediate impact of importation might be felt by the country exporting drugs to the United States. John Calfee of the American Enterprise Institute proposes the most extreme scenario, stating that if wholesalers replaced 15 percent of U.S. pharmaceutical revenues with Canadian product, for instance (assuming their drugs sell for two-thirds the U.S. price, on average), manufacturers would lose 5 percent of their U.S. revenue.

But Dr. Alan Sager of the Boston University School of Public Health believes that allowing Americans access to foreign drug markets could actually increase pharmaceutical revenues.[88] His conclusions are based on a simple economic principle: when prices of desired goods are low, people typically buy more goods. When prescription drug prices are low, more people will be able to afford them, and thus a greater overall volume of pharmaceutical purchases will be made. Dr. Sager's hypothesis is borne out by relevant research. According to a recent study by the Kaiser Family Foundation, individuals living under the poverty threshold with drug coverage used twice as many prescription drugs as individuals without drug coverage,[89] and while 11 percent of non-elderly adults with insurance reported going without needed prescription drugs, 26 percent of non-elderly adults without insurance reported forgoing necessary medication.[90]

A second potential economic impact would be the effect of reimportation on investment in research and development and the benefits accruing from that investment (if there were to be a decline in industry profitability). Dr. Drew Senyei, managing director and general manager of Enterprise Partners Venture Capital, voiced these concerns at a California Healthcare Institute (CHI) conference in February. He argued, "For early-stage investors like myself, [the returns] must represent a four times or greater multiple over a five- to

[88] Alan Sager and Deborah Socolar, "Do Drug Makers Lose Money on Canadian Imports," Health Reform Program, Boston University School of Public Health, Data Brief No. 6, April 15, 2004.
[89] Kaiser Family Foundation, "Prescription Drug Trends: A Chartbook Update," November 2001.
[90] Kaiser Family Foundation, "Medicaid and the Uninsured: The Uninsured and their access to Health Care," January 2003, http://www.kff.org.

eight-year period or a 25-35% IRR [internal rate of return]…we must continue to reward the entrepreneurs by free-market pricing; otherwise, they will not continue to innovate."[91]

But other concepts for the support of research and development can be identified outside the parameters of the U.S. industry's thinking. Donald Macarthur cites manufacturers' data showing that there was a three-fold increase in European research and development from 1985 to 1999, and that UK spending on research and development of pharmaceuticals increased 108 percent between 1990 and 1998.[92]

At the February 2002 conference of the Institute of Health Economics on International Pharmaceutical Policies, Canadians were able to impart their unique experiences. In particular, Don Willison from McMaster University shared information from his study regarding balancing competing health and industrial policy goals in the shaping of national pharmaceutical policy in seven countries. Willison found that an unregulated pricing environment was only one of a set of the elements conducive to attracting investment capital to finance research and development. The remaining elements included "proximity to major markets, a favorable regulatory environment, good public sector research capacity combined with the free flow of information between public and private sectors, a healthy financial environment, [and] strong intellectual property protection."[93]

Willison's view of investor motivations expands upon Senyei's description of investors' financial performance expectations. Willison sees investors as awaiting their return on the investment they made in genomics and proteomics, while there is increased competition for the blockbuster drugs whose profits have supported the research and development for lower-volume drugs. Also of specific relevance to investment in research and development, according to Willison, are developments in intellectual property rights, such as the variations in how genes are patented, country by country (discovery versus invention), and the patent extensions for new indications that will protect some of the more expensive drugs. Any effort to reduce prices impinges upon many diverse agendas. This is likely to be the context that will shape any pharmaceutical industry response toward Illinois state action.

Already, supply has been interrupted to Canadian Internet pharmacies, causing the State of Illinois to look to European sources for personal importation of maintenance drugs. European Union countries have been warned that they might expect a similar response if drugs they have received are subsequently parallel imported. If governments do not explore sanctions for pharmaceutical companies that cut off supply, any attempts to implement importation may create shortages, thereby making actual importation impractical.

---

[91] California Healthcare Institute, "The Economics of Innovation: Global Price Controls and the Future of Biomedical R&D," February 2004, http://www.chi.org.
[92] Donald Macarthur, "Parallel Trading of Medicines in Europe: The Case for a Fair Deal," adapted from the author's previous work in *Consumer Policy Review* of the UK's Consumer Association, Jan/Feb 2001, volume 11, number 1, 6-10.
[93] Institute of Health Economics, "Conference on International Pharmaceutical Policies: A Canadian Reflection," February 2002.

Counterfeiting and Safety Concerns

In February 2004, FDA's Counterfeit Drug Task Force released a report regarding drug supply chain safety and anti-counterfeiting initiatives. The task force examined both "unit of use" (blister pack) packaging as well as tamper-evident packaging, and determined that neither approach should be used alone. FDA also reviewed authentication methods such as the use of different colors of ink, holograms, fingerprints, taggants, and chemical markers embedded in drugs. The most promising approach, they felt, would be to provide a pedigree through reliable "track and trace" technology (available by 2007), which would identify the drug at its point of manufacture with a unique electronic product code number and employ radio frequency identification to follow the drug through the distribution system.[94]

The Illinois delegation learned that in Europe, holograms are generally included in pharmaceutical packaging for lifestyle drugs (such as Viagra, Cialis, and Levitra), which may not be covered by the national health or other insurance plans. Consequently, these drugs are available at higher, non-negotiated market rates, thus making them more desirable to counterfeiters. As noted by Dr. Chaand Nagpaul, a member of the British Medical Association, counterfeiting "tends to happen in relation to drugs like Viagra, slimming [diet] drugs and sleeping tablets, where buying things privately might be attractive."[95]

Both European and Canadian importation offer the special benefit of less vulnerable processing, as pills are not counted out in the pharmacy. Rather, they arrive with two levels of protection: the primary, foil-wrapped blister pack and the box. Information is available on the box and on the label of the blister pack if needed to address potential recall and expiration safety issues.

Current Online Pharmacy Practice in the EU

Introducing a personal importation model would highlight the distinctions between traditional and online pharmacy practice. By definition, "online" refers to the submission of orders to an Internet pharmacist by e-mail, leading to the shipment of the medicines either directly to the orderer or to a pick-up point. This is the mail-order business familiar in the United States but less viable in Europe, where prices are competitive and patients may receive comprehensive reimbursement under their national health insurance system. Possible problems for online sales across borders are the high volume of potential patients who lack Internet skills, potentially tough national and EU rules, and EU pharmacists who may be active in their opposition to personal importation. Practically speaking, while every medicine must have either a license number from an individual country or an EU authorization from the EMEA (European Agency for the Evaluation of Medicinal Products), products not approved locally may be available online.

[94] FDA, "Combating Counterfeit Drugs," February 2004.
[95] BBC News, "Fake prescription drugs warning," June 24, 2004, http://news.bbc.co.uk/1/hi/health/3834007.stm

The most significant early model of online practice in Europe, Macarthur points out, has been Doc Morris (http://www.docmorris.com), which is located in the Netherlands and targets the German market. It sells its drugs at regular Dutch retail prices, 10 percent lower than the German prices. Doc Morris requires that its customers be registered and that its pharmacists receive written prescriptions by mail before they fill them for patients. Just as German pharmacists have opposed Doc Morris, Germany's sick funds have supported the development of a more competitive German market.[96]

Negotiating Prices

Each European government sponsors its own form of national health coverage. Governmental policies determine how much revenue has been raised from taxes and other sources and how that revenue will be used to provide public health services. Once a decision has been made regarding what share of the budget the health plans will receive, the question arises as to the reimbursement for pharmaceuticals. But with the cost of such a large volume of drugs to be purchased at stake, each government has felt responsible for negotiating with the drug companies on behalf of its citizens, and each approach has been distinctive.

For example, the UK's Pharmaceutical Price Regulation Scheme (plan) is "a voluntary profit maximization system."[97] The British government negotiates with each drug company regarding how much profit is to be made by selling its products to the NHS (National Health Service) based on overall corporate profitability, not on each product's margin. A second approach, implemented in the Netherlands, Portugal, and Romania, is based on comparative prices. Comparisons might focus on price increases, the pricing of new products in different countries, or the full set of prices of similar or identical products in other countries. A third approach is evaluative, stressing findings about the specific value of drugs. Australia, Canada, Finland, the Netherlands, and Norway all include some of these considerations in establishing prices by analyzing direct and indirect benefits (compared to the costs of alternative treatments) as well as limitations and risks.[98]

The York Consortium has detailed five specific national approaches to negotiating drug prices:[99]

- *Price cap:* The UK caps corporate profits once manufacturers have priced new drugs. The government also negotiates over any increases.

[96] Donald Macarthur, "Online Pharmacies in Europe: Current Situation, Future Prospects, and Possible Impact," Decision Resources, Inc., October 2002.
[97] Dukes, Haaijer-Ruskamp, de Joncheere, and Rietveld, "Drugs and Money: Prices, affordability and cost containment," World Health Organization, 2003.
[98] Ibid.
[99] York Health Economics Consortium, "Benefits To Payers and Patients from Parallel Trade," May 2003.

- *Reimbursement:* The government in the Netherlands categorizes drugs according to their therapeutic action and intended patient group. The maximum reimbursement price is set equal to the price immediately below the average price for the group. A second indicator is the average price in the UK, France, Germany, and Belgium.

- *Price cap plus reimbursement:* Denmark requires that prices be no greater than the European average, but manufacturers also are affected by the reimbursement rate, which includes a wholesaler margin, a retail mark-up, and a dispensing fee.

- *Reference price:* Sweden has considered cost-effectiveness, impact on the overall drug bill, other European prices (although not the average), and the price in the country of origin (not to be exceeded in Sweden).

- *Modified reference price:* Germany employs a similar referencing group to that used in the Netherlands. Once a new product is introduced, however, it automatically is reimbursable if it is deemed medically suitable for treatment.

Finally, there is a trend exemplified by the French method to trade off higher prices on new potential blockbusters for manufacturer concessions in such areas as price cuts for other products, caps on sales volume, and the introduction of some cheaper generics. It is important therefore to examine any negotiations with manufacturers in a full context, rather than accede to pressure over one specific point of contention. After all, this is how the French, with a small market compared to the United States, are able to operate.[100]

Overall, there is a free market in Europe in the sense that manufacturers are free to sell their products or to withhold them from the market. In fact, the current debate over a proposed pan-European price raises the question of a "free" market. Parallel importers, sick funds, and supplemental insurance funds all oppose a single European price because of their interest in price transparency. The single price is a misnomer, since it would only mark the beginning of rebate negotiations, country by country, which would remove cost and pricing transparency. The result of proprietary rebate negotiations would replicate the undesirable market obfuscation confronted by state Medicaid programs and payers in the United States.

Generics and the European Market

Different European countries regard generics in different manners. In Belgium, generics are pricier than in the United States. And despite the availability of its generic version, Prozac is sold competitively by Lilly in Europe. But certain generics, such as atenolol (the generic for Tenormin), could be imported to the United States from the UK in a highly economical manner.

[100] Macarthur, "Parallel Trading of Medicines in Europe: A Case for a Fair Deal."

The highest penetration of generics into the European pharmaceutical market is in the UK, Denmark, Germany, and the Netherlands.[101] Recently, more regulated countries like France, Italy, and Spain also have become interested. Their approaches toward generics differ. Denmark's reimbursement system will refer only the cheapest available product, and there is a policy of mandatory substitution. In the UK, generic prescribing is promoted in medical education. All prescriptions issued by the National Health Service are written using the generic name. Germany actually has prescribing budgets for physicians, as well as a reference pricing system. In the Netherlands, pharmacists who dispense generics are permitted to keep 33 percent of the difference between the generic and the branded drug. In Ireland, if physicians can create savings by generic prescribing, they are permitted to retain 50 percent of those savings. In 1999, the French health insurance system committed itself to 7 percent generic utilization overall.[102]

Also important to the generic market are developmental policies (also known as Bolar policies) that allow generic research while the brand-name product is still under patent. Such policies allow competitors to start their research regarding the development of a generic drug before the patent on the brand-name drug expires. Therefore, when the patent does expire, those competitors can begin manufacturing and selling their generic drugs immediately. Without these policies, brand-name patent holders can maintain their market monopolies for several years after the expiration of their patents while generic competitors catch up by beginning their research and production processes.

A related issue is the length of time the brand-name patent holder (the innovator) retains "data exclusivity." The data exclusivity period refers to the duration of time during which a generic manufacturer intending to copy a branded drug is not permitted to use data contained in the dossiers of the innovator companies. A proposal by the EU Commission aims to extend the data exclusivity period to ten years, while at the same time introducing a Bolar clause: each innovator company would enjoy ten years of exclusive sales before having to release its data, but competitors would also be permitted to begin their own research before the ten-year period has expired.[103]

Conclusion

While the need to provide Illinoisans with safe and affordable medications identical to the prescriptions they can ill-afford to purchase locally is well understood, there are complex arguments for and against meeting that need that have been exploited to impede the issue at the national level.

[101] Dukes, Haaijer-Ruskamp, de Joncheere, and Rietveld, "Drugs and Money: Prices, affordability and cost containment," World Health Organization, 2003.
[102] Ibid.
[103] Ibid.

A very general example is the misperception honed by the pharmaceutical industry that the issue at hand is about the reimportation of U.S.-manufactured drugs. In theory, these drugs have been exported to lower-priced markets, and allowing them back into the U.S. would be an invitation to dangerous counterfeits. In fact, large numbers of brand name and generic drugs, as well as over-the-counter drugs (OTCs), are already manufactured outside of the United States. Every day, pharmaceuticals are imported from FDA-approved facilities in Europe, Southeast Asia, and Puerto Rico, among other places. U.S. generic manufacturers and distributors are currently importing a number of high-quality generic drugs from manufacturers outside the U.S., especially from low-cost countries such as India and Israel. Despite the pharmaceutical industry's misinformation campaign, the issue is *importation* and it disguises the protection of artificially high prices.

The national discussion is framed in terms of "reimportation." Similarly, this report uses the terms "reimportation" and "importation" virtually interchangeably. They are, however, slightly different terms and it is important to clarify their respective meanings. Were the current legislative proposals enabling "reimportation" to be passed, without recognition of the difference between the two terms, the drafters of the legislation might inadvertently codify the exclusion of many prescription medications being sought. An Illinois policy and program initiative must be developed with an understanding of the real market forces surrounding the importation of drugs, and of both the real—and less substantive—market impacts that have been suggested.

This section has attempted to distill the critical thinking associated with a potential importation market, and to present the research generated by the delegation to assess the importation market as well as pharmacy practices, European price negotiation models, the impact on issues such as pharmaceutical innovation, and the choice of included drugs. This synthesis of economic and industry issues provides a foundation for the design of the Illinois initiative, and may help inform the national debate on drug importation.

The preferred option for the State of Illinois and its residents would be the simultaneous availability of both personal and parallel importation models. By offering access to personal and parallel importation, Illinois's individuals, businesses, and pharmacies could achieve economic benefits through price competition generated by the free market. If Illinois wholesalers and pharmacies had access to lower-cost medications from vetted foreign sources, they could compete with foreign mail-order pharmacies. However, the State of Illinois cannot afford to wait for the implementation of a parallel importation system before proactively addressing the security concerns associated with the current personal importation model (which helps individual purchasers obtain lower-cost prescription medications but lacks safety measures). Therefore, the State should take the steps necessary to ensure the safety of the current personal importation model and work to improve prescription drug access for all Illinois residents.

IV. Findings Regarding European Pharmacy Standards and Practices

The European delegation was asked to determine if the pharmaceutical products produced and distributed in visited countries were safe. The delegation's work built upon the findings of the team previously sent to Canada (see Appendix 2).

The safety of European pharmacy standards and practices was of the utmost importance. The delegation knew it would need to review the regulation of European pharmacy personnel as well as standards and practices for manufacturing, warehousing, and storage. Delegation members also planned to study the conditions under which brand-name maintenance medications were dispensed and distributed, the origination of European prescription drugs, wholesaling and manufacturing practices, and the pharmaceutical approval process in Europe.

Pharmacist Qualifications

The qualifications required by European governments for a person wishing to register as a pharmacist are substantially equivalent to those required to be licensed as a pharmacist in the State of Illinois. Pharmacist candidates must complete a four- to five-year undergraduate degree in pharmacy and a six-month to one-year practical experience working under the direct supervision of a registered pharmacist. The Illinois pharmacy schools offer a six-year program, wherein the sixth year is comprised of a working internship.[104] Upon completion of these education requirements, candidates in both Europe and Illinois must pass a licensing examination that evaluates the candidates' knowledge in multiple pharmacy-related subject areas. The pharmacist members of the delegation were able to discuss, in detail, the various aspects of the practice of pharmacy with pharmacists in Belgium, France, Ireland, and the UK. They were impressed with the level of knowledge and competence exhibited by the European pharmacists. The delegation members concluded that the European pharmacists conducted themselves with the same high level of professionalism and integrity that they would expect from a pharmacist practicing in the State of Illinois. Patients in Illinois could receive similar care from a pharmacist in any one of the visited European countries as they would from an Illinois-licensed pharmacist.

Pharmacy Storage

The storage conditions for prescription medications within all of the pharmacies visited were similar to those of pharmacies within the State of Illinois. Each European pharmacy is required to maintain sanitary conditions and the proper storage of pharmaceuticals. All

[104] According to the Illinois Pharmacy Practice Act of 1987, pharmacy students are required to complete five years of post-secondary study, although many individual school programs require a sixth year of experiential education.

compounding equipment and consumable materials are required to be maintained in good condition. All of the prescription drugs are stored under proper conditions of sanitation, temperature, light, humidity, ventilation, and security similar to the standards set by the Pharmacy Practice Rules and Regulations within the State of Illinois.

Distribution

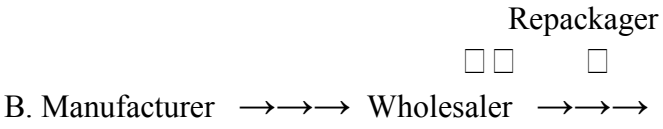
The delegation members noted some differences in the manner in which medications are distributed within the countries visited when compared to the United States. Drug distribution within the United States is complex and can involve many intermediate steps. As FDA itself notes, "In many instances, there can be one or more wholesalers, or even a repackager, who handles the drug before it reaches the retailer. It is in these intermediate steps, particularly when the wholesaler(s) and/or repackager(s) obtain products from sources other than the original manufacturer, that the greatest opportunities for compromising the security of the U.S. distribution system exist."[105] By contrast, Europe has a very streamlined, closed, drug-distribution system. As in Canada, pharmaceutical products in Europe are shipped directly from the manufacturer to the wholesalers or pharmacies. When parallel importers are involved, they relabel the pharmaceutical products, then either place them in the storage facilities of their in-house wholesale division or ship them to an external wholesaler. Significantly, the delegation heard of no counterfeit issues attributed to parallel importation.

Drug distribution systems of the United States, Canada, and Europe are illustrated in figure 2 below.

[105] FDA, "Counterfeit Drug Task Force Interim Report Questions and Answers," October 2003, http://www.fda.gov.

Figure 2
U.S. drug distribution models[106]

A. Manufacturer →→→ Retailer



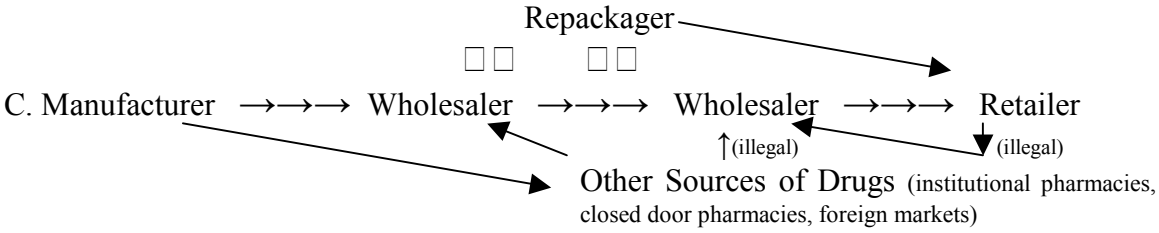
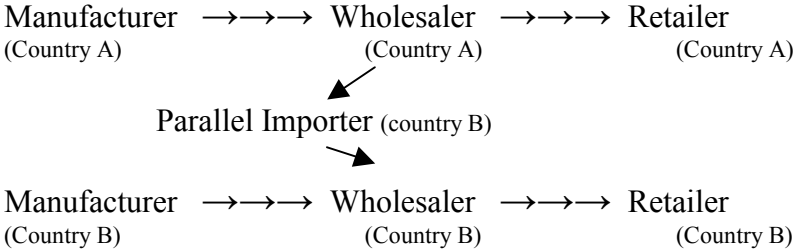


Figure 3
Canadian drug distribution model

Manufacturer →→→ Wholesaler →→→ Retailer

Figure 4
European drug distribution model



[106] Ibid.

Dispensing of Medications

All of the pharmacies visited by the delegation adhered to quality control measures from receipt of a prescription to the dispensing of medication. In the State of Illinois, the quantity of a medication dispensed by a pharmacist generally is the quantity prescribed by the physician (quantity limits may apply based on third-party reimbursement guidelines). Pharmacists in Illinois are typically required to open the manufacturer's original, sealed packaging, which contains a wholesale quantity of pills, and individually count out the number of pills prescribed for the patient. Because pharmacists must open the package, physically count out the pills, place them in a new container, and label that container, the possibility of human error in dispensing is present. In contrast, medications dispensed within the European countries visited are supplied in a pre-counted blister pack, which is packaged within a box. The prescription is dispensed in the original manufacturer's box. The primary packaging is the blister pack, which contains the individual doses. Primary packaging is analogous to unit-dose packing within a hospital setting in the United States. The secondary packaging is the box in which the blister-packed product is contained. The boxed medications dispensed by the pharmacist are not opened prior to or during the dispensing process. As would be expected in the practice of pharmacy, this method of dispensing medication (an unopened box arriving untouched from the manufacturer) reduces the opportunity for dispensing errors.

Except for the major difference of dispensing sealed blister-packed drugs as opposed to our domestic U.S. practice of counting and bottling individual pills, the visited pharmacies dispensed medications in a manner similar to Illinois pharmacies. All of the visited pharmacies utilized computers to process patient prescriptions. As in Illinois, a patient profile is generated. Each patient's medication history, hypersensitivity, and potential drug interactions are stored within the computer to generate the profile. All of the computer software systems used were capable of generating warnings regarding potential drug therapy issues, including drug-drug interactions, drug allergy, over dosage, and overly frequent prescribing of medications.

Regulation of the European Distribution Market

Parallel importers operate within a heavily regulated environment. The scope of the regulations governing their activities is understandable given that the traded products are destined for the pharmaceutical supply chain within the parallel importer's host country. (The exception is the UK, where a parallel importer can export imported product to Ireland.) The consequences of this activity directly impact each country's public health and welfare.

In the participating EU states, parallel importers are required to practice according to the European Union Guide to Good Manufacturing Practices (GMP). This specifically provides compliance and regulatory guidelines for parallel importers or any parties other

than the original manufacturer, who may trade and/or take possession of, repack, manipulate, distribute, or store pharmaceutical products.

These regulations require that parallel importers maintain traceability of their distributed pharmaceutical products and records of the intermediaries to whom they distribute. The following documents must be maintained by the parallel importer to assure traceability: the identity of the original manufacturer; addresses of the original manufacturer; purchase orders; bills of lading (tracking documents between the carrier and shipper); receipt documents; name or designation of the product; manufacturer's batch number; transportation and distribution records; all authentic Certificates of Analysis of the products received, including those of the original manufacturer; and any retest or expiry dates of the products obtained. In contrast, licensed wholesale distributors in the State of Illinois are required to maintain only a record of the name and address of the company from which they purchased the drug, the identity and quantity of the drug purchased, and the date of receipt of the drug. There is no way to determine how many hands the drug has passed through prior to being purchased by the wholesaler.

Regulations concerning repackaging, relabeling, and holding of the product must be performed under appropriate GMP controls and conducted under appropriate environmental conditions to avoid contamination and cross-contamination of products. Stability studies to justify assigned expiration or retest dates must be conducted if the product is being repackaged in a different type of container than that used by the original manufacturer.

Information transfer regulations require that the parallel importer transfer all quality or regulatory information received from the original manufacturer to the customer, and from the customer to the original manufacturer. The parallel importer supplying the repackaged/relabeled product to the wholesaler should provide the name of the original manufacturer, lot number, and expiration dates, and the identity of the original product should be provided to regulatory authorities upon request.

Parallel importers are required to maintain records of all complaints and recalls that come to their attention. If warranted, the parallel importer should review the complaint with the original manufacturer in order to determine whether any further action, either with other customers who may have received the repackaged/relabeled products or with the regulatory authority, or both, should be initiated. The investigation into the cause for the complaint or recall should be conducted and documented by the appropriate party. Where a complaint is referred to the original manufacturer, the record maintained by the parallel importer should include any response received from the original manufacturer.

All parallel importers inspected by the delegation repackaged and relabeled pharmaceuticals. They are therefore considered to be manufacturers. This designation was based upon the definition of a manufacturer as found in each visited country's rules and regulations. This designation is made because the manufacturing of pharmaceuticals can

consist of more than just the drug's production. Repackaging and relabeling pharmaceutical products are considered aspects of manufacturing as well.

In addition to the manufacturing aspect of parallel importation, the delegation also studied wholesale drug distribution. The State of Illinois regulates wholesalers according to the laws and rules of the Illinois Wholesale Drug Distribution 225 Illinois Compiled Statutes 2000, 120/1-185, and Title 68, Chapter VII, Subchapter b, part 1510. The rules require that wholesale distributors also adhere to some federal and state laws regarding wholesale drug distribution. The specialists on the delegation concluded that all but one of the many wholesalers and parallel importers visited would pass a standard inspection by the Illinois Department of Professional Regulation.

The wholesalers and parallel importers fulfilled the following requirements:

- Entities had a valid license to participate in wholesale drug distribution.
- Storage and handling conditions met acceptable standards.
- Facilities were of suitable size.
- Quarantine areas were maintained separately and distinctly from the general area.
- Warehouses were maintained in a clean and orderly condition, free from infestation by insects, rodents, birds, and vermin.
- Drugs were stored under conditions of proper temperature and humidity.
- Room temperature was maintained properly, and appropriate equipment was present to monitor and document storage conditions of pharmaceuticals.
- Secure sites with security systems in place were maintained.
- Prescription drug areas were limited to authorized personnel.
- Distribution records were maintained for a minimum of two years, and included: records of inventories for receipts, distribution, and disposal; sources and provenance of drugs; and the identity and quantity of drugs received, distributed, and disposed of.
- Personnel were qualified via training and education; in each visited parallel import facility, the Qualified Person (QP as a technical qualification) met all of the requirements for experience in the field of pharmaceutical manufacturing.
- Standard operating procedures incorporating the Good Manufacturing Practices (GMP) were utilized for repackaging, relabeling, storage, and warehousing functions.
- Accepted policies and procedures were maintained for the following acts: stock rotation; procedures for recalls and withdrawals of drugs, including governmental agency requested withdrawals, manufacturer withdraws, and replacement actions; procedures for crisis; procedures to remove, segregate, and document the disposition of outdated drugs; and procedures for damaged or outdated drugs, including quarantine and physical separation.

Unlike the citizens of Europe, Americans are completely prohibited from utilizing the parallel importation market to obtain medication at lower prices. For this reason, the Federal Rules and Laws within the United States do not specifically provide guidance regarding parallel importation.

Conclusion

The delegation was charged with determining whether the pharmaceutical products produced and distributed in the visited countries were safe. They determined that all of the pharmacies they visited used effective and appropriate methods to track pharmaceuticals that are dispensed to patients. In conformance with applicable Illinois and host nation standards, the visited pharmacies were able to provide appropriate documentation regarding adherence to drug safety, procurement, dispensing, and counseling. The visited pharmacies fulfilled the requirements of the United States and the State of Illinois.

All of the wholesale drug distributors and the parallel importers visited were required to establish and maintain a chain of custody for each pharmaceutical product shipped. Adhering to this requirement limits the potential for counterfeiting agents to enter the stream of commerce. All of the many visited parallel importation establishments except one fulfilled the manufacturing requirements of the United States regarding relabeling, repackaging, and wholesale distribution. Only one visited operation was determined to be deficient when compared to Illinois standards. This finding supports the delegation's position that any pharmaceutical distribution system should be vetted and monitored, as is necessary in Illinois.

Based upon the delegation's observations of the practice of pharmacy, wholesale drug distribution, and parallel importation within the countries visited, the delegation would recommend that all successfully vetted entities be utilized as sources of pharmaceuticals for the residents of the State of Illinois.

V. Options Analysis, Recommendations, and Implementation

Illinois has the opportunity—and the obligation—to assist its citizens in addressing the safety and costs of prescription drugs purchased online. The State's interest in assuring the safety of prescriptions drugs, as well as the recognition that Internet purchases are growing in response to pharmaceutical pricing in the U.S., are both clear.

The fact-finding trip to Europe helped define the State's options in operational terms, especially as to the parameters of whether pharmaceutical supply could be safely and continuously obtained, and whether use of the European market could be cost-effective at what possibly might be different levels of participation and utilization. Additionally, information obtained by the delegation helped address the State's concern that demand for reimportation would continue to grow whether or not accompanying safety measures were in place.

Option One: Maintain the Status Quo (Unregulated Personal Importation)

The State would initiate no further activity other than to support legislation enabling the expansion of personal importation of prescriptions, recognizing that U.S. and Illinois residents specifically, in increasing numbers, are compelled to seek out less expensive medications from abroad.

Evaluation

While maintenance of the status quo is not a recommended option it reflects the current practice of unregulated personal importation, which has significant risks. While pharmacies in Canada and the European countries visited met essentially the same standards found in the State of Illinois, not all Internet pharmacies are legitimate. Several Internet pharmacies advertise narcotics, do not require a prescription, offer unapproved products, or claim to be Canadian but actually operate from other countries. In this unregulated shadow market, it is difficult for consumers to differentiate between honest sellers and unscrupulous opportunists. Thus, a consumer may not know whether the prescription drugs he or she purchases online come from a licensed pharmacy in a regulated market, like the United Kingdom or Canada, or from a questionable, secondary source in an unregulated market. The current state of federal inaction not only maintains higher prices in the United States, but also exposes domestic purchasers of foreign prescription drugs to a higher risk of buying substandard medications. Providing a regulated alternative to protect our citizens is morally imperative.

Option Two: State-Facilitated Access to Vetted Canadian Internet Pharmacies

The State of Illinois, on its website, could sponsor links to Canadian Internet pharmacies. These would be sites vetted at least initially by Illinois, or vetted by other states (for

which a determination has been made of reciprocity and acceptance). Consumers could interact with these pharmacy sites, independent of further involvement of the State in the process. These sites may or may not operate with contractual or ongoing oversight mechanisms.

Evaluation

Minnesota, Wisconsin, New Hampshire, and North Dakota have all established state websites featuring links to Canadian Internet pharmacies. Yet several of these pharmacies inappropriately shipped generic drugs not approved for sale in the United States.[107] Therefore, simply contracting with a small number of non-domestic pharmacies in one country may not be optimal to ensure quality or continuity of supply. If Illinois depends on a small number of pharmacies to meet all of its needs, and if the majority (or even a significant portion) of those pharmacies default on previously agreed-upon standards, the viability of the entire program may be jeopardized. Securing the participation of a large number of pharmacies in the network would enable the state to drop errant pharmacies from its network without compromising the program. Currently, several large pharmaceutical manufacturers are restricting supply to Canadian pharmacies. Until the State develops sanctions (on its own or in concert with other states) against manufacturers for supply interruptions, reliable availability of supply will remain a problem. This is the reason why Illinois cannot recommend the model proposed in Option Two.

Option Three: The Web-Based Clearinghouse Network

This State could enter a contractual relationship with a non-domestic, PBM-like entity. This entity would perform functions as a clearinghouse for all prescriptions filled through the non-domestic network. The State would provide a referral and link to the clearinghouse's website in exchange for regulated services and adherence to safety standards. The clearinghouse would maintain a network of pharmacy providers in Canada and abroad. The State, through the contract and/or direct vetting and management, would ensure safety and performance.

Evaluation

Option Three is the recommended option for direct action by the State to ensure the safety of Illinoisans already purchasing or contemplating the purchase of prescription pharmaceuticals from Canadian Internet sites. This contractual relationship with a non-domestic, PBM-like entity enables the State to assure the quality and efficacy of its program, and to assure the safety and cost-effectiveness of prescription medications purchased by individuals over the Internet. Under the contract, the State's requirements for standards of operation could be extended to all pharmacy entities within the network. Performance guarantees on quality, as well as ongoing periodic inspections and certification by the State's regulatory agencies, could ensure that medications obtained from network entities are just as safe as those obtained domestically.

[107] Frederic J. Frommer, "Three Pharmacies Shipped Unauthorized Drugs to Wisconsin," *Pioneer Press,* June 16, 2004, http://www.twincities.com.

The costs of regulation and safety assurance could be financed by a small reduction in savings that should be an acceptable tradeoff for providing Illinoisans with the highest assured quality of product and service. The cost of regulation is expected to be less than 5 percent of the potential savings from this program. Further, while personal importation would remain a personal decision for Illinoisans, the State would be fulfilling its obligation in terms of professional and health regulations, and addressing the concerns expressed by FDA. The program development proposal follows the discussion of Option Four below.

Option Four: Parallel Importation

Illinois pharmacies and wholesalers would be able to import certain prescription drugs, which may already have been relabeled, and sell them to Illinois consumers. The range of medications available in this model would be wider than the range included in the personal importation model.

Evaluation

There can be no doubt that, if properly vetted, parallel importing can be safely conducted. Under a parallel importation model, Illinois would only purchase from a State or federally inspected and certified parallel importer rather than take on the task of repackaging in the United States. Vetting on a periodic basis would assure quality, and use of the European parallel importer recognizes the underlying economics of the manufacturing operations observed by the Illinois European delegation.

Both personal and parallel importation are technically illegal under current law, but FDA has chosen to allow individuals to purchase limited supplies of prescription drugs from abroad for personal use. Until the law is changed, however, it would be inconceivable that FDA would permit parallel importation by businesses. The scope of such importation—involving distribution, warehousing, and security—would require FDA's response and involvement.

Recommendations

The report's authors make two recommendations:

1. The State should consider prompt implementation of Option Three, the web-based clearinghouse network.

2. The State should aggressively support national legislation that promotes Illinois and U.S. pharmacies by permitting them to participate in wholesale importation from Canada and Europe (Option Four).

If the recommendation of Option Three is accepted, then the program should be formulated along the following elements. A PBM-like entity would perform functions as a clearinghouse for all prescriptions filled through the non-domestic network. The State would provide a referral and link to the clearinghouse's website in exchange for regulated services and adherence to safety standards. The clearinghouse would develop a network of pharmacy providers in Canada, the United Kingdom, and Ireland. The clearinghouse would develop and maintain a custom website that enables consumers to compare prices for their prescription drugs from different approved foreign sources.

In the first stage of implementation, the recommended clearinghouse model would be structured around an existing network of Canadian Internet pharmacies chosen and vetted by the State of Illinois. This network would be used because these providers have supplied pharmaceutical products to residents of the United States for several years in a safe and reliable manner. At a later time, maintenance of the clearinghouse function may be shifted to, or enlarged to include, additional nations that have been approved by the State of Illinois. During the initial stage of implementation, prescription drugs from Canada, the United Kingdom, and Ireland would be included. This is because a common language—English—makes immediate execution of the clearinghouse model possible.

Why Is a Clearinghouse Model Necessary?

Currently, the U.S. domestic prescription drug market is split between retail and mail order sectors. The retail sector includes the chain drug stores, such as Walgreen's and CVS, as well as independents. (See Appendix 8 for a comparison to European pharmacy regulations.) The U.S. mail-order sector is dominated by PBM owned and operated facilities. Because PBMs negotiate rebates and discounts with pharmaceutical companies for a large number of members, they have access to proprietary pricing information. Approximately 10 percent of the State's employee and retiree prescriptions are currently filled via mail order.

Individuals with prescription drug coverage pay the same co-payment at all retail pharmacies that accept their plan of coverage, and consequently are likely to fill their prescriptions at the most convenient location. Regardless of which pharmacy is utilized, all prescriptions are adjudicated by the same PBM that provides the coverage, and some level of real-time drug utilization review takes place. By contrast, uninsured individuals without prescription drug coverage are likely to shop for the best price, and they may patronize several pharmacies concurrently. This presents an undesirable situation: a prescription filled in pharmacy A that has a significant interaction with a prescription filled in pharmacy B may not be detected until it is too late.

To minimize the risk of drug interaction in patients obtaining medications from different domestic and/or non-domestic pharmacies, the recommended options would utilize a central clearinghouse model. In this model, all non-domestic prescriptions should be channeled through a single entity: a clearinghouse. The clearinghouse should receive and

have on file patient medical history, current medications, allergies, and other information necessary to identify potential drug interactions and to help the patient avoid receiving a medication to which he or she may be allergic. All prescriptions received should be entered into the network computer database and checked for potential interactions, allergies, and other complications. If there were any questions or concerns, the clearinghouse pharmacist should contact the prescribing physician and a resolution should be reached. Only then should the prescription be forwarded to the contracted, non-domestic network physician for review and rewriting as required by local pharmacy practice laws and regulations. Also to minimize the risk of potential complications, it is imperative to require the patient to first fill a 30-day supply of his or her medication from a domestic retail pharmacy. The proposed process would work in the following manner:

- A patient would receive a prescription from a U.S. physician.
- A 30-day supply of the medication would be filled by a U.S. pharmacy.
- After tolerating the medication, the patient would file a prescription refill from the original physician with the clearinghouse. At that time, the patient would also choose which vetted pharmacy he or she would like to utilize based on price (the clearinghouse would allow patients to calculate their best price based on the combination of ordered medications).
- The clearinghouse would enter the information into a database, make certain that the prescribed medication was appropriate for the patient's medical history, and ensure that no drug interactions would take place. Any questions would be referred to the prescribing physician.
- The clearinghouse would then forward the prescription to the contracted physician in the country in which the participating pharmacy is located, and the prescription would be rewritten according to local requirements.
- The prescription would be forwarded to the participating pharmacy, which would fill it and send it directly to the customer.

How Would the Proposed Options Be Implemented?

The expansion of services by the contracted network should use a phased approach. The first phase should be designed to assist individuals who wish to access lower-cost medications. The second phase should be designed to lower prescription drug costs for the State of Illinois, Illinois taxpayers, and businesses. This could be accomplished by providing incentives to state, county, and municipal employees and retirees for utilizing the non-domestic network to obtain their medications. Illinois businesses should be assisted and encouraged to enroll their employees in custom network programs, thereby reducing the cost of providing prescription drug benefits to their employees. The state could also explore the possibility of allowing members of its Circuit Breaker Pharmaceutical Assistance Program to access the non-domestic network. The potential savings achieved could be utilized to expand services or increase coverage.

The second phase, with its emphasis on access for additional Illinois residents, may require an extension of the provider network to support expanded program capacity. Pharmaceutical sourcing could be extended to the additional countries visited by the European delegation (Belgium, France, Germany, and the Netherlands), and could potentially be extended to additional English-speaking countries such as Australia and New Zealand (subject to passage of pending federal legislation and Illinois inspection and approval).

Subsequent to program implementation, the Illinois Department of Public Health (IDPH) should monitor the supplies shipped to residents. IDPH should also order medications from the network pharmacies and have them inspected and analyzed at periodic intervals.

The non-domestic network should be required to provide a number of safety precautions and consumer protections:

- To participate in the program and to sell to Illinois residents, the clearinghouse and the participating pharmacies should have to agree not to require a liability disclaimer from their customers.
- Every pharmacy that participates in the program should have to agree to initial and periodic inspections by the State of Illinois. Any facility not meeting standards specified in the Illinois Pharmacy Practice Act would be excluded. Violations and substandard performance could lead to suspension or dismissal from the network.
- Each network pharmacy should be required to maintain individual patient profiles including current diagnosis, medical history, current medications, allergies, and U.S. physician's name, address, and telephone number.
- Each prescription should be screened using standard drug-interaction software used by U.S. pharmacies; the patient's U.S. physician should be contacted for all clinically significant interactions.
- Prescription drugs should only be sold pursuant to a valid prescription issued by a U.S. physician; reasonable efforts to assure validity of the prescription should be undertaken by the clearinghouse, and may include calling the U.S. physician or checking public databases to confirm the physician's name, address, and telephone number.
- The patient should be required to remain under the care of a U.S. physician at all times; additionally, under Option Three, the patient's prescription would undergo an additional review by a second physician, duly qualified and licensed in the country or province where the prescription is filled.
- The clearinghouse should have to agree to provide a money-back guarantee if for any reason the ordered prescription drugs do not reach the consumer.
- A prescription must have been filled by a domestic pharmacy first for 30 days, and tolerated by the patient, before it should be filled by a participating pharmacy.
- Toll-free telephone access to a pharmacist should be available 24 hours a day, 7 days a week, to answer medication-related questions.

- Bilingual (English-Spanish) customer service should be available 24 hours a day, 7 days a week. Other languages could be added based on need.
- Dispensing should be strictly limited to products deemed appropriate for importation; an approved list should be available to each network pharmacy, and website offerings should be limited to this list.
- Generics unavailable in the U.S. should not be dispensed.
- Medications should be dispensed in childproof containers, although certain packaging (such as blister packs) may make this impractical; patient approval is to be obtained in such situations.
- The patient should be informed before dispensing a brand-name product for which a generic equivalent is available in the U.S. at lower cost.
- Prior approval from the patient and his or her U.S. physician should be required for dispensing a product marketed under a different brand name (Seroxat vs. Paxil, for example, or Reactine vs. Zyrtec).
- All medications should be dispensed in sealed containers.
- Prescription label requirements include:
  - Name/address/phone number of pharmacy
  - Name of patient
  - Name of prescriber
  - Date dispensed
  - Name/strength of drug/quantity/dosage form
  - Directions for use
  - Initials of pharmacist and technician
- Patient counseling leaflets should be provided with each prescription, original and refill.
- Pharmacies should comply with all local laws and regulations in their country of residence.

What Drugs Would Be Included/Excluded?

The non-domestic mail-order model is financially feasible when a three-month supply of drugs is ordered. This is similar to the current domestic mail-order system. The larger volume (of three months' supply) lessens the burden of having to pay for the shipping costs, which are estimated at $15 per shipment. If the cost differential of the medication is less than the shipping cost, it would be more cost effective to purchase the medication from a local retail pharmacy. The non-domestic mail-order model has some issues that should be addressed, such as the time needed to fill the order and deliver it to the end user.

1. The medications most suitable for non-domestic mail order are those that are not immediately required or medications needed to treat chronic disease states. Medications such as antibiotics would not be candidates for non-domestic mail

order or the personal importation model. These may, however, be included in a parallel importation model.

2. Medications that are priced lower in the domestic market than in the country from which they would be imported would not be included. Most generics fall into this category. Generics in general are sold at a lower price in the United States than they are in Canada. Europe presents some interesting situations regarding generics; these are discussed elsewhere in this report. In short, generics in the UK were found to be more cost effective than in any other European country visited. Due to the low cost of generics in the United States, the importation of a single generic from the UK is not likely to be cost effective. However, if a generic prescription is included in a shipment with other brand-name medications ordered from the UK, the overall cost could be much lower compared to the U.S. market.
3. Due to the potential for exposure to extreme temperatures during shipping, injectable medications, as well as bio- or recombinant DNA technology-based products that may spoil during transit, may not be suitable for personal importation. These products may be eligible for parallel importation, since monitoring mechanisms are available to monitor and assure temperature control during bulk shipping.
4. Controlled substances and habit-forming medications are naturally excluded from the personal importation model. These may be included in a parallel importation model.
5. Medications not yet available in the United States in generic form are to be excluded due to patent issues under both personal and parallel importation models.
6. Medications not approved by FDA must be avoided. Only FDA-approved medications (molecules) in approved doses should be available for importation under both personal and parallel importation models.
7. Lifestyle and OTC medications approved in the United States may be included under both models if financially viable.

Likely Participants and Incentives for Enrollment

At an individual level, U.S. residents with no prescription drug coverage (including the hundreds of thousands of uninsured Illinoisans) will be most motivated to import medications. Employees facing high co-payments or co-insurance will also be likely to use the personal importation model if an incentive, such as a waiver of co-payment, is offered.

The costs to employers of offering prescription drug coverage to employees have been rising by almost 20 percent each year since 2000, and this trend is expected to continue throughout 2004.[108] Rising costs have led most benefit plans to either increase premiums or employees' co-payments for medications. In the United States, it is not unusual to see

[108] The Segal Company, "2004 Segal Health Plan Cost Trend Survey," http://www.segalco.com/publications/surveysandstudies/2004trendsurvey.pdf

co-payments in the range of $15 to $20 per month per prescription for formulary brand, and $25 to $40 per month per prescription for non-formulary brand drugs.

Large self-insured businesses could save 10 to 15 percent of their current costs of providing prescription drug coverage by reimbursing employees for medications obtained through the personal importation model. The savings would depend on levels of employee participation (which are contingent upon ease of system use, list of included drugs, and incentive plans). Employers could waive shipping costs for individuals in order to increase participation. Large-scale participation in such a program could effectively dampen the national trend of the drastically and consistently increasing costs of providing prescription drug coverage.

Many small businesses are not able to provide prescription drug coverage to their employees because of high costs; however, these businesses could add this coverage by participating in the proposed personal importation model. The State of Illinois should facilitate this process by helping small businesses join the program. A link for small businesses should be provided on the State's website allowing access to model agreements and protocols, and assisting in determination of co-pays and benefit caps. The State's proposed model would permit small businesses to stretch their prescription drug dollars, thereby creating drug coverage for more employees.

Illinois pharmacies and wholesalers would be likely participants if there were no barriers to parallel importation. However, most initial participants will likely be wholesalers and chain drug stores. Due to rigorous record keeping and chain-of-custody requirements, individual drug stores may find it difficult to import directly. However, they could participate by purchasing the lower-cost, parallel-imported product from wholesalers and dispensing it to their customers. It is likely that a portion of the overall savings would be passed on to the end user.

To successfully provide greater access to lower cost medications from vetted non-domestic sources, both parallel and personal importation models should be made available to the customer buying the prescription. If a viable personal importation model is not available, or is restricted to a single country, there is less incentive for pharmacies to pass on the savings to the customer.

VI. Financial Summary

Savings Estimation Methodology

A list of the top 100 brand-name prescription drug line items[109] shipped to the U.S. (excluding antibiotics, generics, narcotics, drugs requiring refrigeration, narrow therapeutic index drugs, and others that may not be suitable for importation) was requested from a Canadian mail-order vendor. One line item—Coumadin 5mg—was deemed inappropriate for importation and thus deleted from further review. Utilization for the remaining 99 line items for the State's Quality Care Health Plan and selected Managed Care lives (individuals) managed by Caremark was determined (for the first quarter of 2004). This utilization was converted to the Canadian stock bottle sizes shipped to the U.S.

Irish, UK, and UK parallel import prices were obtained from Irish and UK wholesalers. Belgian prices were obtained from the publication "Tarief Der Farmaceutische Specialiteiten," published by Association Pharmaceutique Belge. French prices were obtained from a mail order website based in France. Canadian and U.S. prices were obtained from websites in each country between June 15 and June 19, 2004. Not all line-item prices were available at this time from countries other than Canada.

The methodology for developing the potential savings per year follows:

1. The Illinois plan volume (prescription drug utilization of 99 selected prescription line items in the first quarter of 2004) was re-priced for each country. All prices reflect all expenses described in Option Three and the subsequent program description, except for shipping costs.
2. The differentials (usually savings) were then annualized for 213,113 individuals covered by the State's plan.
3. The resulting projected savings (based on drug-price differentials only) were then converted to costs per 100,000 people (by dividing the State's projected savings by 2.13).
4. The projected savings reflect the costs of all available pharmaceutical items considered in table 3 (including negative values). The projected savings are conservatively estimated because prescriptions with higher than domestic net cost would not be filled.
5. The initial savings projection was then adjusted to reflect the general population. A number of factors—such as plan design, age and gender distribution, and coverage status—affect prescription drug utilization by the general population. For these savings projections, utilization by the general public was estimated at 50 percent of utilization of the State's plan, to account for inclusion of the higher-utilizing retiree

[109] A prescription drug line item refers to a brand-name prescription drug of a specific strength. A drug may appear more than one time on the list, but at separate strengths.

populations in the State plan data. Therefore, the projected savings (from step 3) were multiplied by 0.5.

6. Savings projections by country are presented in table 3. Savings are limited to drugs for which pricing information was available (*Number of Brand Drug Line Items)*. Savings for all drugs in all countries would be higher except in Canada, where all prices were available and evaluated.

Table 3
Savings per 100,000 Cash-Paying (Rx-Uninsured) Individuals[110]

Country (or source)	Number of Brand Drug Line Items	Percent Savings Range Compared to U.S. Web Prices	Potential Savings per Year (in millions of dollars)
Belgium	19	8% to 85%	$8.34
Canada	99	-6% to 78%	$28.95
France	19	-6% to 91%	$3.86
Ireland	60	-23% to 71%	$14.75
United Kingdom (domestic supply)	52	-17% to 77%	$10.27
United Kingdom (parallel-imported supply)	65	-10% to 83%	$16.44

As evidenced by the range of savings listed above, not all brand medications are of lower cost in the countries reviewed. This may happen when the costs of review and handling by the clearinghouse, and the costs of meeting the requirements (such as review and approval by a non-domestic physician), are greater than the savings that would be achieved by purchasing from a non-domestic supplier.

The savings are exclusive of any shipping charges the personal importer would incur. The average cost of shipping from Canada and Europe is estimated at $15 per shipment of up to five prescriptions. Based on the experience of the Canadian vendors, the average shipping quantity is between 2.5 and 2.8 prescriptions per shipment.

[110] These projected savings require that the limited set of brand-name drugs be imported from different countries.

The projected savings numbers are for the cash-paying population (individuals without prescription drug coverage). Individuals with prescription drug coverage are usually required to pay a co-payment or coinsurance in addition to their portion of the premiums, and do not bear the full cost of the prescription medication. Such individuals are not likely to experience the magnitude of savings listed above.

Employers, who are large purchasers of prescription drugs for their employee groups, usually contract with a PBM to manage the prescription drug benefit plan. Since employers benefit from the PBM negotiated discounts and rebates, the prescription drug cost to them is lower than it is to an individual without the coverage. The employers are likely to achieve significant cost savings if they structure their prescription drug benefit design to include a non-domestic source. The magnitude of savings would depend upon their current net cost, the cost of providing incentives to employees to use the non-domestic source, and the extent of employee participation.

Economic Impact

The economic impacts of personal and parallel importation on the State can be variously estimated, and these impacts may be both positive and negative.

Under the proposed personal importation model, Illinois retail pharmacies will lose some prescriptions to non-domestic pharmacies. But only a limited number of drugs (high-cost brand drugs) would be appropriate for this type of model; all other drugs—such as those used for short duration [antibiotics], controlled substances, generics, etc.—must be filled at the retail pharmacy. It is also important to note that even without the implementation of a personal importation model, purchases of brand-name maintenance medications have been trending toward domestic mail order, as mail-order services offer lower prices to the payers than retail pharmacies. Additionally, pharmacy costs associated with brand-name maintenance medications are relatively high, and pharmacies typically receive a low margin on the sale of such drugs. Most retail pharmacies receive their highest margins on generic drugs and short-duration drug therapies; these types of drugs are less suitable for a personal importation model.

Also under a personal importation model, Illinois retail pharmacies would be eligible to be selected and compensated for providing coordinated cognitive services to individuals who are insured and enrolled in PBM benefit plans. The primary care pharmacist model funding to the pharmacies would be $2.2 million to $2.7 million for the first twelve months of employee/retiree program implementation. However, while the primary care pharmacist model is suitable for individuals in a plan where all prescriptions—domestic retail and mail order—are channeled through a PBM (the non-domestic vendor would be required to report all prescription sales to the primary care pharmacist), it may not be applicable to the uninsured population.

Illinois pharmacies will benefit significantly if, through importation, they can access lower-cost medications from abroad for dispensing. Parallel importation would enable a much broader range of medications to be imported and made available to Illinois consumers at lower cost, benefiting the residents and the pharmacists.

The economic benefits of greater access to affordable medications and greater compliance with physicians' prescriptions would provide advantages to individuals without prescription drug coverage, governments, small employers who may not provide health coverage and cannot afford absences due to illness, and to physicians and hospitals that may provide less uncompensated care. An additional economic benefit is that individuals who procure non-domestic prescription medications would have greater discretionary income to spend locally.

The consequences on a macroeconomic level may be more easily quantified on a maximum basis. Were unlimited supplies available for importation, and if *all* of Illinois residents used personal importation to meet their medication needs for maintenance prescription drugs, then the maximum potential savings, estimated with fairly conservative assumptions, approach $1.9 billion. While the participation in personal importation would never reach 100 percent, these savings would accrue to the general public, state and local governments (and taxpayers), and to employers providing prescription drug coverage for their employees from non-domestic sources.

Cost Savings Projections

The cost savings projections are divided into two major groups: residents who have employer-provided prescription drug coverage and residents who lack drug coverage. Detailed drug cost and utilization data for the employees and retirees covered by the State of Illinois were used to extrapolate cost savings projections for employers. Cost savings projections for the estimated 23 percent of Illinois residents who lack prescription drug coverage were obtained by discounting the utilization data of State employees and retirees by 50 percent.

The projected 12-month net savings for the State of Illinois and its employees and retirees ranges from **$94.9 million to $112.9 million** depending on the country of drug origin. This projection assumes that employees and retirees are able to obtain the selected list of program drugs from Canada, Ireland, or the United Kingdom, and assumes the State will *not* require the employee or retiree to pay any co-payment or shipping costs as an incentive for participation. In addition, the net savings amount assumes that 4 percent of program savings is used for program administration and the Illinois Primary Care Pharmacist Model. Furthermore, this savings is divided between the State and the employees and retirees of the State: the State's savings would be between $49.3 million and $67.3 million (depending on the country of origin) and the employee/retiree savings amount would be $45.6 million.

The projected savings for all Illinois employers (excluding the State of Illinois) is $950.6 million. State of Illinois employee and retiree data was provided by the State's PBM for the first quarter of 2004. This data reflects recent pharmaceutical price and utilization increases, and was adjusted based on information provided by the PBM for the average age and experience of beneficiaries of the State when compared to the PBM's other clients.

Projected savings for the Illinois uninsured is estimated to be $851 million. This projection was developed by obtaining current drug prices from U.S.-based Internet sites and comparing those prices to those of Canada, Ireland, France, Belgium, and the United Kingdom. The total number of uninsured (for prescription drugs) was estimated to be 23 percent of 12,653,544, the total number of Illinois residents.[111]

The estimated maximum potential savings for the State of Illinois is **$1.9 billion** for the first full year of program operation (assuming a 100 percent participation rate). If only half of all eligible participants took part in this program, a savings of roughly $1 billion would still be achieved. However, it is unrealistic to believe the pharmaceutical industry will not try to restrict supply wherever possible. It would be necessary to look beyond Europe to achieve full potential savings. To handle this volume, the program could be expanded to additional nations in Europe and, potentially, countries such as Australia and New Zealand.

The loss of domestic U.S. sales to pharmaceutical manufacturers will be significant, while their non-U.S. revenues will rise. Their loss will be the difference between their U.S. and non-U.S. prices. The pharmaceutical industry's absolute utilization is likely to rise due to increased access and compliance attributed to greater affordability of prescriptions. Pharmaceutical manufacturers will also benefit from increased price competition, which hones productivity, a factor from which they have been largely sheltered in the domestic U.S. market.

Conversely, the resulting loss in sales tax revenue from domestic prescription drug sales to state and local government budgets should be neutral. Employers' costs of providing drug coverage could go down, either in absolute terms or as a declining rate of increase, thereby reducing the costs of doing business and enabling other business investment and economic growth. Uninsured individuals who pay the full costs of their prescriptions will reduce their drug expense and release that disposable income directly to other purchases, as will individuals with prescription coverage for which plan co-payments are reduced as an incentive to safe and regulated personal importation. Additional data and analysis is required to fully explore this dimension. But, given that people are expected to see a significant reduction in their drug costs, the total impact for a local community is likely to be positive because the money saved is expected to go back into the community and the state.

[111] U.S. Census Bureau, "Annual Estimates of the Population for the United States and States, and for Puerto Rico: April 1, 2000 to July 1, 2003," http://eire.census.gov/popest/data/states/tables/NST-EST2003-01.php.

VII. Conclusion

The continued development of pharmaceutical products is necessary and desirable, but the prices currently paid by Americans for prescription drugs are utterly unsustainable. A change must arise: a solution to this problem, not a reaction, is needed. Unless and until the pharmaceutical industry is willing to prioritize research and development funding over spending on advertising and executive compensation (see table 4), thus preserving its valuable research function while creating affordable prices, U.S. residents will have no choice but to continue to seek necessary, lower-cost medication outside the country's borders.

Based on the extensive review and study of available options, the State should offer all Illinoisans access to a regulated personal importation model through a network of State-inspected and monitored pharmacies as quickly as possible. As discussed in this report, many Illinoisans are and have been participating in an unregulated personal importation system for years without the benefit of State inspection, oversight, and purchasing power. An organized, regulated personal importation model would permit Illinois residents and businesses to purchase low-cost prescription medication from regulated, inspected, and secure facilities located in countries where the pharmacy regulation standards are as stringent as those of Illinois. Participants would save millions of dollars in the process.

Illinois's proposed personal importation model provides its residents with the option of obtaining a 90-day supply of approved program drugs at savings of 25 to 50 percent. This option would permit many patients to end the cycle of choosing between food or rent and the brand-name medications they require for a decent quality of life. Personal importation will reduce the need for husbands and wives to choose which partner will take medication on a given day, because they cannot afford to pay for medicines for both.

By acknowledging and addressing the current reality of unregulated reimportation, state and federal legislators can take the first step toward the development of a coordinated reimportation program, thereby ensuring the safety—and improving the health outcomes—of Illinoisans from all walks of life.

Table 4
Pharmaceutical Industry Revenue Allocations, 2000[112]

			Percent of Revenue Allocated to:		
Company	**Revenue (Net Sales)**	**Executive Compensation (Exclusive of Unexercised Stock Options)**	***Profit (Net Income)***	***Marketing/ Advertising/ Administration***	***Research and Development***
Merck	$40,363,000,000	$26,454,600 (Executive VP)	17%	15%	6%
Pfizer	$29,574,000,000	$40,191,845 (Chairman)	13%	39%	15%
Bristol-Myers Squibb	$18,216,000,000	$6,924,102 (Executive VP/CFO)	26%	30%	11%
Pharmacia	$18,144,000,000	$9,305,888 (Senior Executive V.P.)	4%	37%	15%
Abbott	$13,746,000,000	$6,484,284 (Retired President/COO)	20%	21%	10%
American Home Products	$13,263,000,000	$27,008,927 (Chairman/CEO)	-18%	38%	13%
Eli Lilly	$10,862,000,000	$18,788,703 (Chairman/President/CEO)	28%	30%	19%
Schering-Plough	$9,815,000,000	$21,444,020 (Chairman/CEO)	25%	36%	14%
Allergan	$1,563,000,000	$13,271,881 (Corporate VP/Pres., R&D)	14%	42%	13%

[112] All information in the table from Families USA, "Off the Charts: Pay, Profits and Spending in Drug Companies," July 2001, http://www.familiesusa.org.

VIII. Acknowledgments

The authors of this report and the State of Illinois would like to thank the government agencies, businesses, trade groups, industry associations, and the many individuals of Belgium, Canada, France, Germany, Ireland, Luxembourg, the Netherlands, and the United Kingdom who gave their time and provided information and analysis for this report. Their generosity and openness are enormously appreciated. Without their support, this report would not have been complete.

IX. Appendices

Appendix Number	Source	Title	Description
1.	World Health Organization	Health Spending and Health Outcome Data from the World Health Organization	Contains data regarding money spent on health care and corresponding core health indicators
2.	Office of the Special Advocates for Prescription Drugs	Report on Feasibility of Employees and Retirees Safely and Effectively Purchasing Prescription Drugs from Canadian Pharmacies	Examines the feasibility of enabling participants in the State of Illinois' employee and retiree health benefit programs to purchase a specified set of prescription medications from Canadian vendors
3.	U.S. Congress	Cosponsors of H.R. 2427, Pharmaceutical Market Access Act of 2003	Lists the cosponsors of H.R. 2427
4.	U.S. Congress	Cosponsors of S. 2328, Pharmaceutical Market Access and Drug Safety Act of 2004	Lists the cosponsors of S. 2328
5.	Office of the Special Advocates for Prescription Drugs	Members of the European Delegation	Lists the members of Illinois's European delegation
6.	Office of the Special Advocates for Prescription Drugs	Countries Visited by the European Delegation	Lists the countries visited by European delegation
7.	Illinois Department of Professional Regulations	The Illinois Pharmacy Practice Act of 1987	Outlines the rules and regulations set down by the Act
8.	Pharmacy Group of the European Union (PGEU)	Pharmacy Ownership and Establishment in the EU	Addresses pharmacy ownership and establishment in EU member countries

9.	European Commission Internal Market DG	Conditions for the Operation of a Community Pharmacy in EU Member States	Lists the conditions for the operation of a community pharmacy in EU member states
10.	Office of the Special Advocates for Prescription Drugs	Contacts and Facilities	Lists the countries visited, meetings held, and facilities visited by the European delegation
11.	Office of the Special Advocates for Prescription Drugs	Initial Research Issues and Questions	Summarizes issues and questions considered by the European delegation
12.	Office of the Special Advocates for Prescription Drugs	Brand-Name Drug Line Items Most Frequently Imported from Canada	Lists the drugs most commonly imported from Canada by U.S. residents
13.	Office of the Special Advocates for Prescription Drugs	Criteria for Evaluation of Alternatives	Lists the criteria used by the delegation to evaluate alternatives

Appendix 1: Health Spending and Health Outcome Data from the World Health Organization

Country	***Per capita health spending (in U.S. dollars)***	***Life expectancy (at birth)***	***Infant mortality rate (per 1,000 live births)***	***Under-five mortality rate (per 1,000 live births)***
Belgium	$1,916	77.8	4.9	6.0
Canada	$2,102	79.1	5.1	6.0
France	$2,067	79.1	4.5	5.5
Germany	$2,408	78.0	4.4	5.3
Ireland	$1,586	76.3	6.2	7.1
Netherlands	$2,012	78.1	5.2	6.3
United Kingdom	$1,783	77.0	6.0	6.9
United States	$4,540	76.8	7.2	8.5

Source: World Health Organization, Core Health Indicators, 2004. The above chart reflects data from the year 2000.

Appendix 2: Report on the Feasibility of Employees and Retirees Safely and Effectively Purchasing Prescription Drugs from Canadian Pharmacies

This report can be accessed at: http://www.affordabledrugs.il.gov/feasibility.cfm

Appendix 3: Cosponsors of H.R. 2427, Pharmaceutical Market Access Act of 2003

Cosponsors are listed in the order in which they lent their support.

June 11, 2003
Walter B. Jones Jr. (R-NC)
Christopher Shays (R-CT)
William J. Janklow (R-SD)
Thomas E. Petri (R-WI)
Jack Kingston (R-GA)
Jo Ann Emerson (R-MO)
Doug Bereuter (R-NE)
Tom Osborne (R-NE)
Peter Hoekstra (R-MI)
Roscoe G. Bartlett (R-MD)
Nick Smith (R-MI)
Ron Paul (R-TX)
John J. Duncan Jr. (R-TN)
Anne Northup (R-KY)
Wayne T. Gilchrest (R-MD)
Dana Rohrabacher (R-CA)
Dan Burton (R-IN)
Jeb Hensarling (R-TX)
Rahm Emanuel (D-IL)
Barney Frank (D-MA)
Collin C. Peterson (D-MN)
Jim Ramstad (R-MN)
Dennis R. Rehberg (R-MT)
Ernest J. Istook Jr. (R-OK)
Henry E. Brown Jr. (R-SC)
Charles H. Taylor (R-NC)

June 16, 2003
Michael K. Simpson (R-ID)
Steve King (R-IA)
Maurice D. Hinchey (D-NY)
Thomas H. Allen (D-ME)

June 19, 2003
Jeff Flake (R-AZ)
Thomas G. Tancredo (R-CO)
Trent Franks (R-AZ)
John B. Shadegg (R-AZ)
Kevin Brady (R-TX)
John Abney Culberson (R-TX)

June 24, 2003
Rosa L. DeLauro (D-CT)
Patrick J. Toomey (R-PA)
Chris Van Hollen (D-MD)

July 8, 2003
Dennis J. Kucinich (D-OH)
James R. Langevin (D-RI)
Christopher H. Smith (R-NJ)
Zach Wamp (R-TN)
Bernard Sanders (I-VT)

July 15, 2003
Gerald D. Kleczka (D-WI)
Jim DeMint (R-SC)

July 18, 2003
John B. Larson (D-CT)
John W. Olver (D-MA)
Wm. Lacy Clay (D-MO)
Joseph Crowley (D-NY)

July 23, 2003
Albert Russell Wynn (D-MD)
Martin Frost (D-TX)
John F. Tierney (D-MA)

Appendix 4: Cosponsors of S. 2328, Pharmaceutical Market Access and Drug Safety Act of 2004

Cosponsors are listed in the order in which they lent their support.

April 21, 2004
Olympia J. Snowe (R-ME)
Edward M. Kennedy (D-MA)
John McCain (R-AZ)
Thomas A. Daschle (D-SD)
Trent Lott (R-MS)
Debbie Stabenow (D-MI)
Lincoln D. Chafee (R-RI)
Tim Johnson (D-SD)
Mark Lunsford Pryor (D-AR)
Russell D. Feingold (D-WI)

April 22, 2004
Mark Dayton (D-MN)
Charles E. Schumer (D-NY)
Dianne Feinstein (D-CA)
Bill Nelson (D-FL)

April 26, 2004
John F. Kerry (D-MA)
Patrick J. Leahy (D-VT)

April 27, 2004
Richard J. Durbin (D-IL)
Barbara Boxer (D-CA)

April 29, 2004
Barbara A. Mikulski (D-MD)

May 4, 2004
Carl Levin (D-MI)

May 6, 2004
Herb Kohl (D-WI)

June 9, 2004
Daniel K. Inouye (D-HI)

June 14, 2004
Hillary Rodham Clinton (D-NY)

June 15, 2004
Blanche Lincoln (D-AR)

June 18, 2004
Arlen Specter (R-PA)

June 22, 2004
James M. Jeffords (I-VT)

Appendix 5: Members of the European Delegation

1. Ram Kamath, Pharm.D., and Scott McKibbin, Special Advocates, Office of the Special Advocates for Prescription Drugs
2. Eric Whitaker, M.D., MPH, Director, Illinois Department of Public Health and Chief Medical Officer of the State of Illinois
3. Jonathan Dopkeen, Ph.D., Assistant Director of Public Health
4. Joseph Bogdan, Pharm.D., J.D., pharmacist, Illinois Department of Public Health
5. Daniel A. Kelber, JD, legal counsel, Illinois Department of Professional Regulations
6. Yashwant Amin, R.Ph., Ph.D., Director of Drug Compliance, Illinois Department of Professional Regulations
7. Robin Dwyer, policy analyst, Department of Human Services
8. Thomas Londrigan, J.D., Chief Legal Counsel, Office of the Governor

Appendix 6: Countries Visited by the European Delegation

Belgium
France
Germany
Ireland
Luxembourg
The Netherlands
The United Kingdom

Appendix 7: The Illinois Pharmacy Practice Act of 1987

The Illinois Pharmacy Practice Act of 1987 can be accessed at:
http://www.ildpr.com/WHO/phar.asp

Appendix 8: Pharmacy Ownership and Establishment in the EU

For a copy of this report, please contact the Office of the Special Advocates for Prescription Drugs.

Appendix 9: Conditions for the Operation of a Community Pharmacy in EU Member States

For a copy of this report, please contact the Office of the Special Advocates for Prescription Drugs.

Appendix 10: Contacts and Facilities

The delegation held meetings with and inspected facilities in each country as listed below:

IRELAND

Inspected pharmacies and wholesalers.
Met with one parallel importer/wholesaler.

UNITED KINGDOM

Duncan Hill
Health Promotion Facilitator
National Health Service
Greater Glasgow National Health Service Board

Donald Macarthur
Secretary General
European Association of Euro-Pharmaceutical Companies

Martin Harvey-Allchurch
Head of Executive Support
European Medicines Agency (EMEA)

Anthony Humphreys
Head of Sector
Regulatory Affairs and Organisational Support
European Medicines Agency (EMEA)

Met with and inspected parallel importers and wholesalers.
Inspected pharmacies.

FRANCE

Jean-Jacques Des Moutis
Président
Conseil Regional d'Ile-de-France

Laurent Gadot
Chef de Projet

Mutualité Française
Direction de la Santé

Met with and inspected Internet-based mail-order pharmacy.

GERMANY

Nicole Jeannot
Leiterin des Referates: Pharmaziewesen
Saarland

Met with parallel importer/wholesaler.

BELGIUM

Flora Giorgio-Gerlach
Secretary General
Pharmaceutical Group of the European Union

Rebecca Taylor
Information Officer
Pharmaceutical Group of the European Union

Philippe Brunet
Head of Unit
Pharmaceuticals: regulatory framework and market authorizations
European Commission
Enterprise Directorate-General

Dr. Philippe Swennen
Project Manager
Association Internationale de la Mutualite

Rita Kessler
Project Manager
Association Internationale de la Mutualite

Christian Elsen
President
Société Scientifique des Pharmaciens Francophones

ir. Serge Wuestenberghs

Directeur Général
Alpha Répartition

Bernard Bailleux
Vice-President
Association Pharmaceutique Belge

Met with wholesaler, inspected pharmacy.

HOLLAND

Wil Toenders
Apotheker
Farmaceutisch Adviseur
College voor zorgverzekeringen (CVZ)
Vice-President
Association Pharmaceutique Belge

Appendix 11: Initial Research Issues and Questions

Central Policy Issue:

Can Illinois residents and businesses obtain safe and effective prescription medication at lower overall cost by purchasing from Europe?

Potential Research Issues	
***Related Issues:* policy issues over which we have control**	***Underlying Issues:* contextual issues that are beyond our policy control**
Safety	
How does the public perceive the issue? How aware is the public of the facts?	To what extent can we educate the public?
What can we do to counteract counterfeiting rates, both at home and in Europe?	What are the current counterfeiting rates, both at home and in Europe?
Are U.S. pharmaceutical practice standards (including warehousing, storage, and transportation) equivalent to or exceeded by EU facilities?	
How do we know the proposed process is safe?	
At which stage(s) does quality assurance enter? Where is testing done? Whose responsibility is it?	
What are the patient issues at the retail level? • Polypharmacy, drug allergies, duplication, drug utilization review	
Where will patients receive counseling in each model (personal v. parallel importation)?	
	How is a prescription approved in the EU?
	Are prescriptions produced in a facility approved by a U.S. treaty-approved (or legally equivalent) agency?
	What is the chain-of-custody process?
	How does the non-domestic physician intervene in the script process?
	Are there differentials regarding the classification of prescriptions?
	How do EU facilities conduct recalls and expirations?

Feasibility	
What are the current U.S. legal issues, and how might those affect the proposed process?	What current legal issues in the U.S. are beyond our control?
What are the logistics of purchasing prescription drugs from Europe?	How are drugs currently purchased in Europe?
How will language differences affect communication and labeling?	Will language be an insurmountable barrier?
How will the time difference affect how we conduct business in Europe?	
How will we determine the range of drugs available (90 days v. 30 days) under a different model?	
Can appropriate labeling be provided by the host countries, for both parallel wholesale and personal importation models?	
Can appropriate packaging be provided by the host countries, for both parallel wholesale and personal importation models?	
How do we envision a personal retail importation model?	
What is the potential for a pharmacy/wholesaler importation model?	
How will we determine the quantity of drugs available for exportation?	
	Which regulatory issues in the host countries might affect our process? • Chain of custody • Storage/warehousing • Patent rules/issues • International industry protections
	Will a full range of prescriptions be available in the host country?
	What are the parallel importing structures, and how are they standardized (or do they differ)?
	What secondary markets or structures are in place for wholesaling and resale?
	How is the pharmaceutical industry structured in Europe? How does it operate?
	What political incentives would host countries have to participate?

Costs and prices of drugs	
How much money can be saved by utilizing a European importation model? By the State? By individuals? By businesses?	
How could this plan help states nationwide?	
What opportunities exist for U.S. industries (generics export)?	
	What will be the actual impact of cost on research and development?
Legal and legislative questions	
What is the current U.S. national legislative debate?	How will we be affected by the U.S. national legislative debate?
What is FDA's current task force activity?	How will we be affected by FDA's current task force activity?
What are the current actions in Illinois regarding legal waiver requests?	How will current Illinois actions regarding legal waiver requests affect our proposed process?
Miscellaneous issues	
What constituencies will be affected? • Pharmacies • Wholesalers • PBMs • Insurers • Payers • Insured residents • Uninsured residents • Physicians • Professional associations • Academics (MDs) • Lobbying groups	How will these constituencies respond? • Pharmacies • Wholesalers • PBMs • Insurers • Payers • Insured residents • Uninsured residents • Physicians • Professional associations • Academics (MDs) • Lobbying groups
	How will the Medicare Modernization Act and the prescription drug cards affect our analysis?

Appendix 12: Brand-Name Drug Line Items Imported Most Frequently from Canada

For a copy of this list, please contact the Office of the Special Advocates for Prescription Drugs.

Appendix 13: Criteria for Evaluation of Alternatives

Criteria	
	Direction & Scale
Effectiveness	
Safety and accuracy of dispensing and receipt	1. Better than US 2. = US 3. < US
Continuity of supply	Probability of supply constraint: 1. Low 2. Moderate 3. High
Cost effectiveness	$ Savings: 1. High 2. Moderate 3. Low
Savings	Absolute dollars, Not relative
Costs	
Infrastructure Development	$ Expense 1. Low 2. Med 3. High
Implementation	
Maintenance of the processes over time	
Feasibility	
Ease of Implementation	Ease of Implementation: 1. High 2. Moderate 3. Low
Complexity for consumer	Ease for Consumer: 1. High 2. Moderate 3. Low
Political ease or difficulty	Political Ease: 1. High 2. Moderate 3. Low
Likely opposition and/or consequences	Adversity: 1. Low 2. Moderate 3. High
Timing	
Lead time to policy action/ implementation	1. Short 2. Moderate 3. Long
Time to effectiveness (e.g., savings)	